"ESTIMATION OF ENDOTRACHEAL TUBE SIZE BY THE PHYSICAL INDICES BASED FORMULAE VERSUS ULTRASONOGRAPHY IN PAEDIATRIC PATIENTS POSTED FOR SURGERY UNDER GENERAL ANAESTHESIA: A RANDOMISED COMPARITIVE STUDY"

By

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Dissertation submitted to the

B.L.D.E. (DEEMED TO BE) UNIVERSITY
SHRI B. M. PATIL MEDICAL COLLEGE
HOSPITAL AND RESEARCH CENTRE
VIJAYAPUR, KARNATAKA

In partial fulfilment of the requirements for the degree of

DOCTOR OF MEDICINE
IN
ANAESTHESIOLOGY

Under the guidance of

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ABBREVATIONS

ETT- EndoTrachealTube

USG- Ultrasonography

ID- Internal diameter

OD- Outer diameter

GA- General Anaesthesia

mm- millimetre

cm- centimetre

ASA- American Society of Anaesthesiologists

CT- Computed Tomography

MRI- Magnetic Resonance Image

H_2O- water

3D- three dimensional

AP- Anteroposterior

m/s- meter per second

MHz- Megahetrz

IV- intravenous

ECG-electrocardiogram

NIBP- Non-invasive Blood Pressure

SPO_2- Oxygen Saturation

S.D- Standard Deviation

mg- Milligram

kg- Kilogram

mL- Millilitre

hrs- Hours

min- Minutes

n- Number of Subjects

p- ‘p’ value

Sl. No.- serial no

ABSTRACT

Background: Choosing appropriate size EndoTrachealTube (ETT) is a salient aspect in paediatric anaesthesia for successful intubation. Inappropriate size of ETT leads to many complications. In paediatric age group the narrowest diameter of the upper airway is the subglottic region and it determines the size of ETT to be inserted. This randomised comparative study was conducted to compare the estimation of ETT size by Ultrasonography with the physical indices formula based method in paediatric patients undergoing surgeries under general anaesthesia.

Aim: This study was conducted to appreciate the role of ultrasound in determining the appropriate size of uncuffed ETT in paediatric patients posted for surgery under general anaesthesia.

Objectives: To calculate ETT size by Cole s age based formula (ETT ID in mm=age/4+4),

to calculate ETT size by height based formula(ETT ID in mm=height in cm /30+2),

to calculate ETT size by ultrasonographic estimation of subglottic diameter(ETT OD in mm=subglottic diameter in mm), to assess the positivity of leak test at different inflation pressure, to assess the incidence of inadequate ventilation, aspiration and laryngospasm

Methodology: This randomised comparative study was conducted on 93 ASA I and II patients of either gender aged between 5-12 years posted for elective surgeries under GA. The patients were randomly selected and divided by computer generated random number tables in to three groups with 31 patients in each group. In Group A ETT size was calculated using age based formula (ETT ID=age/4+4), in Group B ETT size was calculated using height based formula (ETT ID in mm=height in cm /30+2) and in Group C ETT size was calculated by ultrasonographic estimation of subglottic diameter(ETT OD in mm= subglottic diameter in mm). Data was analysed using chi-square test and 't' test.

Results: Significant difference was observed in positivity of leak test among the three groups:

At Inflation pressure<10 cm H_2O : In Group A and Group C leak test was never positive, where as in Group B it was positive in 3patients (9.7%), at 20-30 cm H_2O :In Group A leak test was positive in 5 patient (16%), in Group B leak test was positive in 7 patients(22.6%) and in Group C it was never positive, at 10 – 20 cm H_2O : In Group A leak test was positive in 26 patients (84%) , in Group B leak test was positive in 21 patients (67.7%) and in Group C leak test was positive in 31 patients (100%).The percentage of successful intubations in Group A was 84% Group B was 67.7% and in Group C was 100%

Conclusion: Ultrasonography is a better tool to estimate the size of uncuffed ETT than compared to age based and height based formula in paediatric patients

KEY WORDS: USG , Endotracheal tube, Paediatric.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

INTRODUCTION

Endotracheal intubation plays a major role in airway maintenance and for adequate ventilation to carry out various surgical procedures without any complications. Endotracheal tube size selection plays an important role in paediatric age group as their airway is more vulnerable to intubation associated complications. [1, 2, 3]

Intubation with a large sized tube may cause upper airway trauma leading to edema, laryngospasm and stridor whereas intubation with a small sized tube may result in insufficient ventilation, increased risk of aspiration, leak of anesthetic gas leading to poor end tidal gas monitoring and pollution of operating room environment. [1, 2, 3]

In paediatric age group the smallest diameter of the upper airway is the subglottic region and it determines the size of endotracheal tube to be inserted. [3,4]

Cole s age based formula (ETT ID=age/4+4) is usually used for uncuffed tube selection in paediatric age.[2] Height based formula (ETT ID in mm=height in cm /30+2) are also in use which often fails in proper size prediction in pediatric age group as the anatomy tends to change with age which may end up in repeated laryngoscopies. [2]

Recently ultrasonography has gained popularity in perioperative airway management.

Ultrasonography is a real time tool for airway assessment which is simple, portable, non invasive without any risk of radiation exposure .It has various clinical applications in upper airway such as estimation of pediatric ETT size and double lumen tube size, to detect endotracheal tube placement, detection of subglottic stenosis, assessment for difficult intubation and evaluation of post extubation stridor, to direct percutaneous tracheostomy and cricothyroidotomy. Studies have shown that measurement of transverse diameter at the level of cricoid can be used for prediction of ETT size. [5,6,7,8]

Several studies have been conducted on the use of ultrasound in ETT size selection which conclude that ultrasound is a feasible and accurate method for selection of ET tube. But very few studies have compared the use of ultrasound with the conventional formulae method in determining the ETT size for pediatric patients posted for surgeries under general anaesthesia.

Hence the present study was conducted to know if the ultasonographic estimation is better than the conventional age and height based formula used in paeadiatric patients to predict ETT size for surgeries under general anaesthesia. The comparison was made in terms of size of selected ET tube, positivity of air leak test and occurrence of complications like inadequate ventilation, aspiration and laryngospasm.

AIMS AND OBJECTIVES OF THE STUDY

AIM: To appreciate the role of ultrasound in determining the appropriate size of uncuffed ETT in paediatric patients posted for surgery under general anaesthesia.

OBJECTIVE :

- To calculate ETT size by Cole s age based formula(ETT ID in mm=age/4+4)
- To calculate ETT size by height based formula(ETT ID in mm=height in cm /30+2)
- To calculate ETT size by ultrasonographic estimation of subglottic diameter(ETT OD in mm=subglottic diameter in mm)
- To assess the positivity of leak test at different inflation pressure
- To assess the incidence of inadequate ventilation, aspiration and laryngospasm

REVIEW OF LITERATURE:

PROGRESSION OF INTUBATION OVER THE PERIOD

In 1858, French paediatrician **Eugène Bouchut** created the technique for non-surgical orotracheal intubation to relieve the respiratory distress caused by laryngeal obstruction due diphtherial psuedomembrane.[9]

In 1880, Scottish surgeon **William Macewen** detailed his utilization of orotracheal intubation instead of tracheotomy for general anaesthesia using chloroform.[10]

In 1913, **Chevalier Jackson** was the primary person to announce a high rate of successful tracheal intubations using direct laryngoscopy.[11]

Another explorer in this field was **Sir Ivan Whiteside Magill** who started the technique of awake blind nasotracheal intubation, use of Magill forceps, the Magill laryngoscope blade and number of equipments to administer volatile anaesthetic agents.[12,13]

In 1943 **Sir Robert Reynolds Macintosh** presented a curved laryngoscope blade which till today is most commonly utilized for orotracheal intubation.[14] By using digital technology to create glottis view, video laryngoscopes are being produced to make tracheal intubations easier.[15,16]

In 1930 red rubber tubes with invariable internal diameter(ID)was presented by **Sir Ivan Magill** which were commonly used until plastic endotracheal tubes were presented in 1959 by **Mr David Sheridan**. The utilization of uncuffed endotracheal tubes in patients below 8 years of age is in accordance with the developing airway anatomy.[17]

HISTORY OF ULTRASONOGRAPHY

In 1974 **Lazzaro Spallanzani** was the primary person to propose experimental proof that non audible sound existed surrounding us and speculated that bats traverse in the night using sound waves.[18]

In 1880, the point of interest revelation within the field of ultrasound by **Pierre Curie and Jacques Curie** was the piezoelectric effect, the fundamental scientific concept behind ultrasonography.[19,20] In 1915, **Paul Langevin** created the primary transducer hydrophone which was utilized amid the First World War to distinguish submarine and icebergs.[19]

Karl Dussik (neurologist and psychiatrist) was the primary doctor to utilize ultrasonography in 1942.[18,19]He detected brain tumors utilizing ultrasonography, but later numerous ventriculograms appeared to be mere artifacts as the brain is fully encompassed by bone.[19]

2D B-mode in ultrasonography was introduced **by Douglass Howry and Joseph Homes** in 1950.[21]

In the field of obstetrics and gynecology ultrasonography was introduced in 1958 by **Ian Donald**.[20]

Krause and Soldner made moving pictures conceivable with real time process in 1965**.**[19] Flow imaging was feasible with duplex sonography in 1985.[21]

Daniel Lichtenstein spearheaded point of care of lung ultrasound in ICU in 1989.[22] Since 1995, 3D ultrasonography has extended the boundaries within in the medical field.[19]

ULTRASONOGRAPHY IN ANAESTHESIA

Ultrasonography in anaesthesia was primarily utilized by **La Grange** in 1978 for supraclavicular blockade of brachial plexus.[19] This was the primary act of using sonographic approach for regional anaesthesia.

The primary report on direct sonographic visualization in regional anaesthesia was issued in 1994 by **Kapral**.[23]

In the field of anaesthesia for central venous cannulation, arterial cannulation, regional anaesthesia and transesophageal echocardiography ultrasound is widely being used.[24] Role of ultrasound in airway screening and management is remarkable.

ULTRASONOGRAPHY FOR ENDOTRACHEAL INTUBATION

Ultrasonography has extensive useage with respect to endotracheal intubation.To begin with it is use to evaluate the location of ETT and for estimation of appropriate size of ETT.

In 1986 **Slovis and Poland** used USG for placement of ETT tip in 16 neonates.[(25)]

In 1987 **Raphael et al** showed that USG has taken the place of radiographs for ETT placement, this study was done on 24 intubated patients.[(26)]

Hand held USG was utilized for evaluating ETT placement by **Chun et al** (2004).[(27)]

ULTRASONOGRAPHY FOR SUBGLOTTIC DIAMETER ESTIMATION AND SIZE OF ETT

USG for calculating subglottic diameter was first used at Montreal Children's Hospital, Quebec. Assessment of USG and a new videobronchoscopic technique was done in 2000 by **Giguère et al** in rabbit model.[(28)]

The same group went ahead to translate their animal research to evaluate subglottic diameter in children in double-blinded, prospective clinical study in 2002. **Husain et al** in this study used USG and videobronchoscopy for estimation of subglottic diameter to conclude that the USG measurement were smaller than videobronchoscopy.[(29)] But USG has gone far ahead to measure the same due to ease and availability.

Chidananda Swamy MN et al (2004) reviewed the applied aspects of anatomy and physiology of paediatric airway and suggested to have a good knowledge of difference between an adult and a paediatric patient for conduct of safe anaesthesia.[(30)]

In paediatric patients **Sibasaki** (2010) concluded that suitable size ETT can be choosen by utilizing USG to measure the subglottic airway diameter.[(31)]In his study it was found that, ultrasound was superior in anticipating correct ETT size than the routinely used age- and height-based formulas.

For the management of intensive care and perioperative cases usefulness of ultrasound was shown by **Kajekar** in 2010.[32]Role of USG in evaluating and managing difficult airway has been confirmed by many evidences. With proper understanding of sonoanatomy, there is increasing clinical application of ultrasonography in airway management in anaesthesia and intensive care.

Mandeep Singh (2010) has reviewed the sonographic details of the anatomic information of airway and has numerous potential clinical applications.[33] They could not visualize epiglottis in 29% (seven of 24) of volunteers in parasagittal plane because of acoustic shadowing by hyoid bone.

Ultrasonographic imaging method has off late been developed as new, convenient, portable, non-invasive implement for evaluating and managing airway, which was portrayed by **Kundra et al** in 2011.[34]

Prasad et al in 2011 compared USG with CT as imaging tools for assessment of airway structures. They found that sonography could visualize all of the structures as reliable as computed tomography.[35]

Chou in 2011 concluded that tracheal rapid airway examination by ultrasound for endotracheal tube placement for emergency intubation is feasible as it can be performed rapidly and considered as secondary confirmation method of endotracheal tube placement.[36]

To assess the use of point of care ultrasound in prediction of difficult laryngoscopy **Adhikari** in 2011performed a pilot study. The sonographic measurements of anterior neck soft tissue were greater in the difficult laryngoscopy group compared to the easy laryngoscopy group at the level of the hyoid bone.[37]

Schramm in 2012 measured minimal transverse diameter of subglottic airway by ultrasound facilitates selection of the appropriate ETT in paediatric patients and may reduce the number of re-intubations.[38]

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Or et al (2013) studied multiplanar 3D ultrasound images and compared visually with corresponding MRI and cadaver anatomical sections to assess the anatomy of the upper airway and measure the subglottic and tracheal diameters in adults. They found strong correlation for the AP diameter measurement and moderate correlation for the transverse diameter measurement of the subglottic space, and a strong correlation for the transverse diameter measurement of the upper trachea, in the ultrasound and MRI .[39]

Hiruma et al in 2015 reported a case of detection of bronchial intubation using lung ultrasound in an infant which was not previously identified by auscultation.[40]

Litman R S et al (2002) conducted a study in children between 0-14 yrs who presented for elective MRIs can under deep sedation. A total of 99 patients were finally enrolled in the study. He acquired MRI images and transverse and AP diameters at three levels of larynx i.e.at vocal cord level, cricoids level , one level in between. They found that the relationship between transverse and AP diameters at all levels including cricoid level were maintained during development. Transverse diameters were narrower than AP diameters at all levels above cricoids and in most patients at cricoids level .There is linear increase in transverse and AP diameter with age, finally giving a conical shape with apex at level of vocal cords .The AP diameter was constant hence giving a cylindrical appearance .These patients were sedated and unparalysed. The shape of larynx was found to be conical in the transverse diameter with the apex at the level of cricoids region in cadaveric specimens. The difference in anatomy in the living and cadaveric larynx was attributed to be due to the atonicity in the cadaveric specimen and variation in the dimensions of vocal cords with respiration in spontaneously breathing patient. Further, they concluded that though the larynx is the narrowest at the vocal cord level in sedated, unparalysed patients, the rigid cricoids ring is functionally the narrowest part.[4]

Suominen P et al (2006) conducted a study in 218 patients who underwent operations under GA aged between newborn to 9yrs age. After induction of anaesthesia and paralyzing patients, tracheal intubation was done with ETT whose size was chosen by the attending anaesthesiologist .Post intubation, the leak pressures were measured. Post extubation adverse events like prolonged barking cough, obstructed inspiration or expiration, subcostal or sterna retractions, fall in saturation or heart rate upto10%, requirement of muscle relaxants, reintubations, lidocaine, nebulization with epinephrine were noted. They found that the incidence of post extubation complications were more in patients with leak pressures at 25cm of H_2O compared to patients with leak pressures <25cm of H_2O(19%vs9%).They concluded that two factors that significantly increased the post extubation complications were experience of anaesthetist less than 6 months and leak pressures at 25cm of H_2O.Hence appropriate size ETT should be inserted in patients especially paediatric patients as large size tube with leak pressures at or above 25cm of H_2O may lead to post extubation complications.[5]

Lakhal K et al (2007) conducted a study in 19 healthy adult volunteers (Females 9, Males10) to measure the transverse diameter of subglottic area by using MRI and ultrasonography. Patients with pre existing laryngeal pathology and those having contraindication to MRI were excluded in the study. Independent operators were appointed to assess measurements by both the methods. Operator who assessed the measurement ultrasonographically was trained in 15 laryngeal ultrasonographic measurements MRI T1 weighted measurements were taken both in sagittal and coronal planes and generated the image of cricoids cartilage in transverse plane. Ultrasonography was done with the patient in supine position taking slow respiration with constant flow to avoid any respiration induced changes in upper airway diameter . Only transverse diameter was taken as AP diameter using ultrasound is not measurable as acoustic shadow of air column obscures the posterior wall. They found that MRI measured transverse diameter of cricoid cartilage is smaller than the AP diameter of cricoids cartilage (mean transverse diameter is15±2mm and mean AP diameter is 19±3mm) with p value<0.05 . Using ultrasound transverse diameter of the cephalic half of cricoids cartilage is measured as cephalic is narrower than the caudal part. They compared the transverse diameters between two techniques using Bland-Altmann analysis and linear regression. Bland-Altmann analysis showed a bias of 0.14mm with precision of 0.33mm using ultrasound. Linear regression between ultrasound measured diameters and MRI measured diameters showed a strong correlation with r valve 0.99 and p<0.05. Calcification of larynx is an important limitation for measuring the transverse diameter of cricoids in older adult patients. They also concluded that Ultrasonography can be a useful option in selecting appropriate ETT size in infants and children where cartilages are not calcified, more differences in airway dimensions are expected and correct ETT placement is crucial in them.(6)

Bae J-Y et al (2011) conducted a study on 141 children of age <8yrs.The usefulness of ultrasonograpghy in selecting the correct uncuffed endotracheal tube in paediatric patients was evaluated. In 41 patients, after induction and paralysis, transverse subglottic diameter was measured using ultrasonography. Tracheal intubation was done with correct ETT size that allowed an audible leak between 15-30cm H_2O.Using linear regression, they derived a formula based on the measurement of subglottic diameter to predict the correct ETT size. In100 children, the initial ETT size was selected after randomly assigning them into 2 groups. In one group, ETT was selected based on ultrasonographically derived formula, ETT ID=(0.705*subglotticdiameter)–0.091 (r20.925andpvalue<0.001)and in the other group the age based formula (age/4+4=ETT ID) was used. The leak pressures were measured by separate investigators blinded to the study. Final ETT which allowed audible leak between 15-30 cm of H_2O was considered as the correctly sized tube. Ultrasonography determined tube size resulted in correct tube placement in 60 out of 100 patients (60%). Age based formula Resulted in correct tube selection in 31% only.(8)

Gupta K (2012) conducted an observational study in 112 patients aged between 3 to 18 yrs with normal airway posted for surgery under general anaesthesia with endotracheal intubation. They measured the transverse diameter at the level of subglottic region using ultrasound before induction. Patients were awake in sniffing position and were asked to breath slowly to avoid any respiratory induced changes in larynx during the study. Patients were then induced, paralysed and intubated with ETT whose OD was equal to that determined by ultrasound. After intubation leak pressure was measured ,tube was considered appropriate if there was a leak between 10 – 20 cm H_2O .If resistance was felt during passing of tube or if leak pressure post intubation were more than 20 cm H_2O it was replaced with 0.5 mm smaller tube .They found that ETT size predicted by age based formula successfully predicted tube size only in 35% of cuffed tubes, formula was not specified. Strong correlation was seen between ultrasound measured diameter with clinically fit ETT outer diameter Bland Altman analysis showed a rate of agreement between Clinically fit ETT size and USG measured ETT size as 98% with p<0.001.They got a mean clinically fit ETT inner diameter between 3-6yrs as 5.4±0.2 and ETT inner diameter via ultrasound measured diameter as 5.5±0.5. They did not find any difference between age based formulae and ultrasound measured diameters in 3-6 age group. But there was a higher rate of success of selecting the correct size of ETT when using ultra sound in the higher age group (6-18years).[3]

Kim E J et al (2013) conducted a study in 215 children aged between 1-72 months. The primary aim of their study was to obtain the degree of agreement between the US-measured OD-ETT at sub gotitic level and the actual OD-ETT used. The secondary aim was to derive an empirical relationship between the patients biographic parameters (age, weight and height) and the subglottic diameter. After induction of anaesthesia and paralyzing the children, the subglottic diameter was measured using ultrasound . The trachea was then intubated with cuffed ETT size chosen using age based calculation. After intubation they measured the OD ETT inserted using ultrasound at subglottic level. The degree of agreement between the US-measured OD-ETT at SD (subglottic region)and the actual (manufacturer's)OD-ETT using Bland-Altmann analysis showed limits of agreement as 0.71mm and 1.03mm . They concluded that ultrasound can be useful option for measurement of airway distances and hence selection of appropriate endotracheal tube size. They did not find any correlation between the demographic profile and subglottic diameter in children less than 1year of age but the correlation was good in the older age group .They further derived formulae for choosing ETT based on regression analysis of outer diameter with age(in months)and height for children over a year old.[7]

Gnanaprakasam PV, Selvaraj V (2017) conducted a prospective study on 150 patients (2-6yrs) posted for surgery under ASA I and II under GA. Patients were randomly divided into 2 groups.In group A ETT was selected based on ultrasonographic estimation of subglottic diameter,in group B ETT selection was done based on modified Cole's formula. A solid relationship was found between subglottic diameter measured using ultrasound and appropriate ETT's OD, determination of suitable ETT using ultrasound was accurate upto 74.7% were as it was 45.3% when modified Cole's formula was used. Measuring subglottic diameter at the cricoid region by USG is a better means to estimate suitable ETT size when compared to modified Cole's was deduced from his study.[1]

Sutagatti JG, Raja R, Kurdi MS (2017) conducted a prospective study on 75 children (1-14yrs) undergoing elective surgery under ASA I and II under GA.

Measurement of subglottic diameter was done at Pre-anaesthetic evaluation using USG. ETT (cuffed and uncuffed)was choosen based on the calculated diameter. Comparision of clinically estimated tube size was done with, tube size determined by USG and that which was calculated by height and age. Among the three USG was concluded to be the best followed by age based formula. Correlation was not found between the size predicted by height based formula and clinically used tube.[2]

PAEDIATRIC AIRWAY

Preterm babies to children less than 12 yrs of age are included in paediatric category.[41]

The salient point in paediatric anaesthesia is management of paediatric airway. Even very little negligence will in turn cause hypoxemia, bradycardia leading to cardiac arrest and death.[42] Airway is the foremost cause of concern perioperatively in paediatric patients[43], mainly noticed in neonates and infants during induction and emergence. Safe practice of paediatric anaesthesia can be done by correct understanding of anatomy and physiology of upper airway, its changes under the influence of anaesthesia and mastering the idea behind upper airway management .[42] There are lots of variation between paediatric airway and adult airway in terms of shape, size, position, epithelium and other supporting structures.

Until 5 months of age neonates are compelled to breathe through nose,[30] so they completely depend on patent nasal airway for ventilation. By eight years of age it reaches adult proportion.

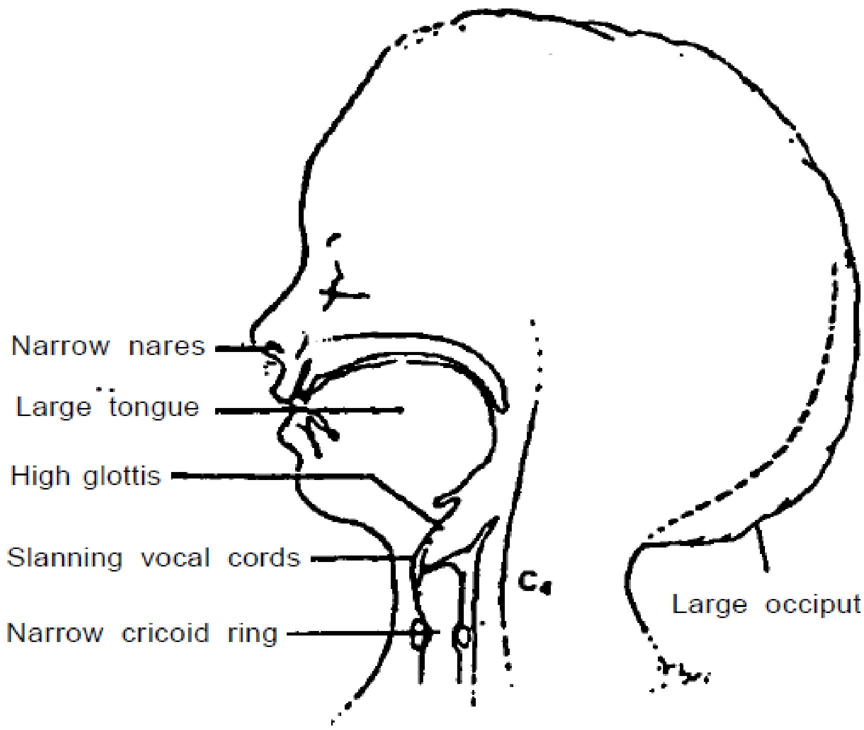


Figure 1: Airway in paediatric age group

Upper airway

Extension: from the nostril and the lips to intersection of larynx and trachea, consisting of nasal and oral cavities, the nasopharynx, oropharynx, hypopharynx or laryngopharynx and the larynx.

Nasopharynx

Extension: from nasal choanae to level of soft palate

Situation: posterior to nasal cavity.

Oropharynx

Extension: from soft palate to tip of epiglottis

Situation: behind the oral cavity

Hypopharynx

Extension: from tip of epiglottis to inferior edge of cricoid cartilage.

Comparably huge head and tiny neck with below par muscle control are seen in infants and neonates.(44) As children have huge occiput placing a pillow under occiput makes it strenuous for laryngoscopy ,therefore placing a pad below neck and shoulder and ring beneath the occiput for balancing the head make it suitable to achieve direct line of sight between eye and larynx.(30)

There is more resistance to air flow due to narrow nares in infants. Oedema, secretions and bleeding further more leads to high resistance. Obtuse angle of jaw is enhanced in infants. Non ossified palate is seen in infants.(30)

Tongue

When compared to oral cavity infant’s tongue is large. So airway obstruction post anaesthesia is common as the tone of the tongue is lost. Laryngoscopic handling of tongue is tough due to its magnitude.(44)

Position of larynx

Center of third cervical vertebra is the position of preterm larynx whereas the infant's larynx is at the level of C3-C4.It is more cephalad as in contrast to adult larynx present at C4-C5.[44] to localize airway structures confirmed that the larynx is higher (more cephalad) in children than in adults and noted that the Hyoid bone is present at the C2-C3 level in neonate till 2 years of age was shown by Magnetic resonance imaging (MRI) and computed tomography (CT) which also confirmed the cephalad position of larynx in children than adults .[44]

Due to cephalad position of larynx:

- Very less gap is present between tongue hyoid bone and epiglottis when compared to adults making the airway more prone for obstruction by tongue
- Strenuous laryngoscopy is encountered due to the angle formed by plane of tongue and plane of glottis opeaning as vision of laryngeal structures is hampered. Hence laryngoscopy in infants is done by straight blade (Miller blade) as it elevates the tongue from field of vision.[45]

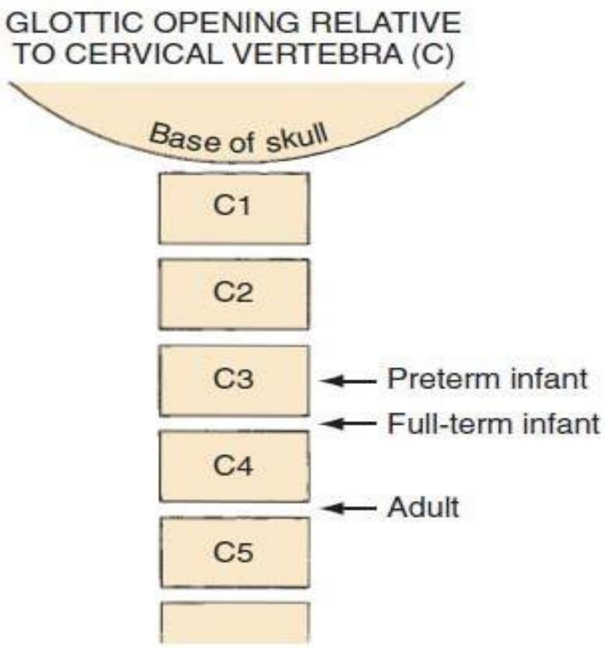


Figure 2: Situation of larynx corresponding to Cervical vertebrae [44]

Epiglottis

In infant during laryngoscopy it is tough to elevate the epiglottis as it is floppy, narrow, omega shaped, huge and its axis is away from trachea compared to adult epiglottis whose axis is parallel to that of trachea ,wide and flat.[(46)]

Vocalfolds

Caudal extension of vocal cords anteriorly than posteriorly is seen in infants in contrast to adults where vocal cords axis and trachea are perpendicular. This changes the entry angle of ETT into laryngeal inlet hampering ease of intubation.[(44)]

Sugglottis

Cricoid is narrowest part in children in contrast to Rima glottis in adults. Subvocal cord level is shown to be the narrowest in children in some studies.[(4)]As the cricoid cartilage is complete ring of cartilage and cannot expand, oedema is frequently seen with the use of oversize ETT which leads to post extubation croup by increasing airway resistance. If the same happens at the subglottic region in infants, the airway compromise is more severe. Cross sectional area decreases about 75% in infants and about 45% in adults if 1mm oedema is formed circumferentially.[(44)]Hence ETT have to be snugly fitting as subglottic stenosis is seen as a squeal to cricoids ulcers. Funnel shaped with a narrow cricoid cartilage and a larger thyroid cartilage. funnel shaped airway with a narrow cricoid cartilage and a larger thyroid cartilage are seen in infants in contrast to cylindrical shape in adults there expeditious growth of subglottic area till 2 yrs, growth becomes linear and reaches adult dimensions by 10-12 yrs.[(47)] Local ischemia and mucosal injury can occur due to pressure of more than 25 mmHg on lateral wall of trachea.[(48)]

Larynx

Unpaired cartilages are epiglottic, thyroid, cricoid and paired cartilages are arytenoids, corniculate and cuniform. Ligaments from base of skull form a sling to these cartilages. Posteriorly articulation of cricoid cartilage with inferior cornua of thyroid is seen, the paired arytenoids which is triangular in shape reclines on the posterosuperior aspect of cricoids cartilage and is safeguarded by thyroid cartilage. In children below 2 yrs of age 60-75% of vocal fold is formed by the cartilaginous glottis.[(44)] Respiration, reflex laryngospasm, movement of larynx during swallowing and phonation is determined by the arrangement of intrinsic laryngeal muscles which is changed by the tissue fold configuration

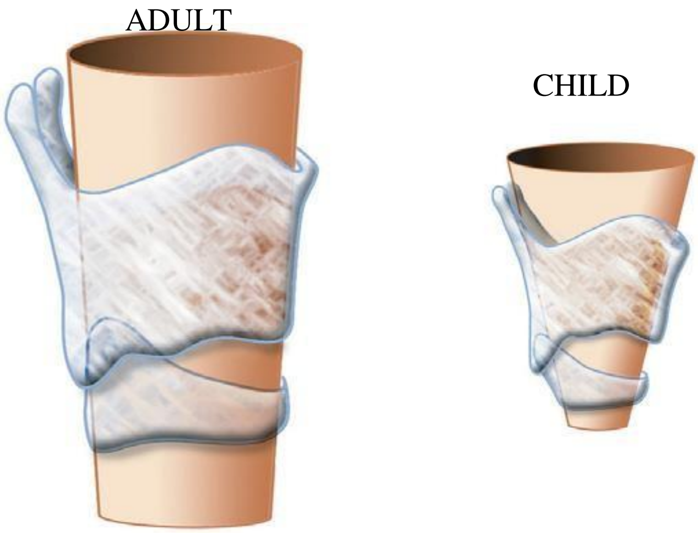


Figure 3 : Difference in shape between adult and paediatric larynx

The laryngeal folds comprises of :

- paired aryepiglottic fold which stretches from posterior aspect of epiglottis to superior surface of arytenoids enclosing the cuneiform and corniculate cartilages.
- The vestibular folds (false vocal cords) joins the posterior aspect of thyroid cartilage to superior partof arytenoids.True vocal cords are seen extending from posterior surface of thyroid plate to anterior process of arytenoid.
- The arytenoids cartilages are crossed over by interarytenoid fold.
- The thyrohyoid fold is from hyoid bone to thyroid cartilage.

Squamous, stratified and pseudostratified ciliated columnar epithelium are seen in the laryngeal and tracheal mucosal membranes which are highly vascular.

Lubrication of the laryngeal folds is by the seromucous glands in mucosa and submucosa. Loose fibrous tissue is present in submucosa due to underlying structures are mostly very loosely attached to mucosa .Firmly adherent mucosa is seen in epiglottis and vocal cords as paucity of submucosa is noted here due to which inflammation above vocal cords is restricted to supraglottis and subglottic inflammation doesn't extend past the vocal cords.[44]

Respiratory physiology

Infants have reduced number of alveoli, elevated diaphragm, flexible horizontal ribs and under developed elastic tissue of lung, which decreases the compliance. Sufficient alveolar ventilation is achieved by increased respiratory rate as alveolar filling time and respiratory gas exchange time is short. As the resistance is high and compliance is low, effort of breathing is high. Their total oxygen consumption is 6-7ml/kg/minute (three times more than adults) due to high oxygen affinity. Perioperative hypoxemia is commonly seen in infants due to their decreased functional residual capacity, immature respiratory control and irregular breathing which is exaggerated by Anaesthesia .Upper airway obstruction, early airway closure and atelectasis are commonly noted in them. [44]

ENDOTRACHEAL INTUBATION

The positioning of pliable plastic tube into the trachea through larynx is known as Endotracheal intubation. Regularly followed is orotracheal route which remains gold standard procedure for airway management.

Aims of intubation: to maintain patent airway, protecting lung from aspiration, allowing leak free ventilation during mechanical ventilation, to deliver gases to and from the lungs

Substitues for endotracheal intubation are laryngeal mask airway, combitube cricothyrotomy and tracheostomy.(42)

Airway resistance (49)

Tracheal tubes gives rise to resistance and increased breathing labour when breaths are taken spontaneously.

Factors governing airway resistance

- Internal diameter of tube: airway resistance is inversely proportional to the inner diameter of the tube and is one of the major determining factor. Other factors which increase resistance are secretions lining the inner portion of tube, passing suction catheter and fibreoptic scope resistance of the.
- Length of endotracheal tube: airway resistance is directly proportion to length of ETT
- Configuration of the tube: Curves in the tube and kinking of tube increase resistance. Connectors also add to the resistance of the tube.
- Dead spaces: natural airway is bypassed by ETT and hence dead space is reduced but mechanical dead space is formed by the ETT and connector.

Available versions of endotracheal tube

Currently ETT's are being made from Polyvinylchloride. They are cost effective, expendable and biocompatible. It has an even surface and conforms to upper airway, bronchoscope and suction catheter can pass through comfortably. Secretions and aspirated material can be seen through due to its transparent nature.

Silicone tubes are costly, can be sterilised and used multiple times.

ETT with micro thin walled high volume low pressure polyurethane cuffs are also available. They have short bevel and murphy's eye is absent.(49,50)

Endotracheal tube design[49,51]

"There are International standard recommendations for material of tube, internal diameter, length of tube, radius of curvature, inflation system, cuff, markings, labelling and packaging.

- The internal and external wall of tracheal tube should be circular.
- Machine end or proximal end receives the connector and projects from the patient. Tube can be cut short to decrease the dead space at this end.
- Patient end or distal end is inserted into the trachea.
- Endotracheal tube have slanted portion at patient end called bevel which faces to left when tube is viewed from its concave aspect.
- Some tubes have hole opposite to bevel called murphy's eye which provides alternate pathway for gas flow if bevel becomes occluded.
- Tubes which lacks murphy's eye are called Magill type tube.
- Radiopaque marker is placed along entire length of tube to determine tube position after intubation."

Uncuffed endotracheal tube[47,48,49,52]

- These are cost effective.
- Monitering of cuff pressure is not required in them.
- Internal diameter of the tube generally determines the resistance and the external diameter determines the mucosal injury, uncuffed tubes have larger diameter and therefore less resistance for spontaneous breathing and mechanical ventilation.
- Chances of occlusion of tube with secretion is comparatively less.

Cuffed endotracheal tube[49,53]

- Cuffed tubes are desirable indicated in patients with increased risk of aspiration,
- They provide improved accuracy of monitoring end tidal gases, tidal volume, lung compliance and oxygen consumption.
- As the cuff seals the gases from escaping, it decreases the contamination of atmosphere
- Chances of tube getting occluded is comparatively more

- Resistance is more due to smaller size. "Poiseulle law governs resistance to laminar flow through a tube, which states that resistance is proportional to the length of the tube and inversely proportional to fourth power of radius" [55]
- Increase in cuff pressure due to over inflation of cuff for prolonged period causes mucosal ischemia.
- Trachea oesophageal fistula are occluded by these.

<u>Microcuff endotracheal tube</u>

It was designed to manage the limitations of paediatric cuffed tube.[50] For good accommodation in paediatric airway the high volume low pressure cuff is placed more distally which reduces the chance of endobronchial intubation. Minimal cuff fold are formed with uniform contact and it provides tracheal sealing with ultrathin polyurethane low pressure cuff. Murphy's eye is absent here.[50,51] Cost is one of the major concern as it is three times costlier than regular ETT.[56]Kinking of tube is seen when tube warms up and becomes soft. Some studies have portrayed that microcuff tubes have lesser sealing pressures than conventional cuff[49] and few of them have reported that the incidence of re-intubation is 1.6% and post intubation croup as 0.4%.[44].Establishment of safety and efficacy of these tubes needs to be shown in larger cohort study

<u>Size of endotracheal tube</u>

Age, height and weight of patient are some of the parameters by which ETT size can be calculated. At 20-30 cm H_2O inflation pressure if leak is detected around the tube, it has to be replaced by one size smaller tube. Ischemic damage to the subglottic mucosa may occur if lateral wall pressure exceeds this.[49]

<u>Endotracheal intubation related complications</u> [42,44,49]

Present with various complications some of which are debilitating to life. Often encountered in paediatric age group due to their anatomical variation

During intubation:

- Unsuccessful intubation: Cannot ventilate cannot intubate (CVCI) may cause hypoxic brain injury leading to death. Cricothyrotomy or tracheostomy can be life saving in such situations.

- Oesophageal intubation
- Endobronchial intubation: can cause hyperinflation and barotraumas in the intubated lung or it can lead to hypoxia due to inadequate ventilation of the other lung. Once recognised ETT should be fxed out by few centimetres.
- Laryngospasm: occurs when intubation is tried in lighter planes of anaesthesia leading to hypoxia. This can be overcome by suboptimal dose of muscle relaxant, deepening the plane of anaesthesia and Larson's manoeuvre.
- Bronchospasm: caused by lighter anaesthesia and hyper reactive airways. It may be blunted by prior administration of anticholinergics, steroids, beta 2 agonist, topical or iv lignocaine and narcotics can be administered in such scenario.
- Pressor response: Increased catecholamine which causes tachycardia, hypertension, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias, rise in intraocular pressure and intracranial hypertension can be encountered during laryngoscopy and intubation Increase in duration of laryngoscopy may result in increased response. Fentanyl 3-4 microgram/kg, lignocaine 1.5 mg/kg, beta blocker like esmolol are used to blunt these reflexes.
- Trauma to airway during laryngoscopy and intubation chances which increases with the use of stylet. Cord avulsions, fractures and dislocation of arytenoids are also seen
- Perforation of oesophagus or trachea: rare complication but can occur with repeated attempts which presents as subcutaneous emphysema. Mediastinitis may occur, which may lead to sepsis and even death. Bronchoscopic identification has to be done and necessary intervention has to be done
- When cervical injury is suspected manual inline stabilization of head must be done during intubation , if not spinal cord and vertebral column injury can be encountered Corneal abrasion, occlusion of central retinal artery of retina and blindness is also seen

Complication with ETT insitu [42]

- Tension pneumothorax: caused by IPPV which can lead to barotraumas or airway perforation during intubation. If it is leading to cardiopulmonary distress, it has to be decompressed using intercoastal drain or wide bore canula.

- Incomplete seal: can be due to ill fitting size tube, cuff leak, inflation valve leak and improper position of ETT. It causes inadequate ventilation and aspiration of gastric content.
- Obstruction of the tube: due kinking of tube, biting of tube or obstruction by blood clot or secretion. It increases airway pressure and resistance.
- Fire during laser surgery.

Complications during extubation[42]

- Suturing of tube to trachea or bronchus can be encountered during pnemonectomy. Direct or fibreoptic examination should be done in such scenario.
- During extubation airway obstruction and laryngospasm can occur.
- Laryngeal oedema: In paediatric age group cricoid cartilage is the narrowest and non-expandable area. Therefore subglottic oedema is often seen in children which presents as inspiratory stridor and causes total airway obstruction later. Humidified oxygen, racemic epinephrine and dexamethasone can be used to treat the same. Reintubation is done if airway obstruction persists.

Complications post extubation[42,49]

- Sore throat: is a minor side effect which usually resolves in 72 hours.
- Laryngeal oedema
- Aspiration of oral or gastric contents
- Laryngeal granuloma: presents as chronic cough and hemoptysis which resolve spontaneously with strict voice rest. Surgical intervention is needed if pedunculated lesion is present.
- Vocal cord paralysis: All the intrinsic muscles of larynx are supplied by anterior branch of recurrent laryngeal nerve which enters the larynx between cricoid and thyroid cartilage. Over inflated cuff compresses the nerve at this region which can lead to nerve palsy. In unilateral injury to the nerve cords remain in adducted position as abduction of cords is restricted and hoarseness of voice is present. Airway compromise requiring reintubation or tracheostomy is seen in bilateral nerve palsy. Usually it recovers spontaneously in days to months.
- Laryngo-tracheal membrane- Leads to respiratory compromise after 24-72 hrs after extubation. Removal of membrane through suction under vision can be done.

- Tracheal stenosis: Ischemia of lateral walls of trachea caused when tracheal cuff pressure more than 25mm Hg leads to destruction of structural integrity of trachea. Fibrous stricture may be formed during the healing process which causes stenosis
.

ULTRASONOGRAPHY[57]

Imaging through USG is done by employing sound waves which propagates through a media by molecular oscillations in similar path as the transmitted wave. Average speed of the propagated wave in soft tissue is 1540m/s and that in bony media is 4080m/s. Frequency of wave used for medical imaging ranges from 2-15 megahertz

Parts of usg machine: probe, computer system and a monitor.

Working principle

Piezoelectric effect: When electric charge is enforced on some substances change of shape is noted conversely electric charge is formed by alteration in the shape when pressure is enforced.

USG probe transducers are formed by piezoelectric material which accomplishes the job of sound transmitter and receiver. Ultrasound signal is generated when electric charge is applied to the transducer which transmits through the tissue and reflects back. Electric signal is formed when the reflected wave returns to the probe and this is transformed into an image which is exhibited on the monitor screen of a computer system by Fourier transformation.[57]

Good axial resolution is got when higher frequency(5-13 megahertz) ultrasound probe is used as the pulse duration is less but their penetration into tissue is very less and hence can only be used for superficial structures. Vice versa low frequency (2-5 megahertz) probes can penetrate upto 30 cm depth which reduces the resolution of the image. Hence while choosing the ultrasound probe both image quality and depth of penetration must be considered.

Table 1:Transducer selection

STRUCTURE	PROBE
abdomen and obstetrics imaging	curvilinear probe with frequency of 3-5 MHz
neck, breast, scrotum, musculoskeletal system	linear probes with frequency of 7-15 MHz
transrectal and transvaginal examination	probe with frequency of 5-9 MHz
Echocardiography	sector probes with frequency 3-6 MHz
imaging of airway.	High frequency linear probes

Acoustic impedance

Sound gets reflected, refracted, scattered, absorbed and transmitted during its transit through soft tissue structures during which characteristic shape and internal architecture of a specific structure and the ones posterior to it is identified .There is pronounced reflection of sound in the area joining tissues of variable acoustic impedance .Ultrasound is effectively relayed through fluids and soft tissues unlike well air and bone.

HYPERECHOIC bright areas are formed by dense structures like bone and calculus as they block the transfer of sound.

HYPOECHOIC grey areas are formed by muscles and fat as there is incomplete transfer of sound

ANECHOIC black area are formed when complete transfer of sound occurs through fluid media.

Impedance variation is highest at the junction between air and bone. Ultrasound is weakly transmitted by air. Potent reflections are formed at tissue air interface as air is poor transmitter of ultrasound, these are called REVERBERATION ARTEFACTS seen as numerous parallel lines with grimy shadowing on the screen. Clarity of deeper structures is impaired by cavity containing air.

Table 2: Appearance of various medium of airway on ultrasound imaging [31,33,34]

Structure	Appearance
Bony structures like sternum, ramus of mandible, mentum and hyoid bone	bright hyperechoic linear structure with hypoechoic acoustic shadow below.
Cartilaginous structures like thyroid and cricoid cartilage	homogeneously hypoechoic.
Muscle and connective tissue	hypoechoic structure with heterogenous striated appearance
Fat and glandular structures	homogeneous and more hyperechoic in comparison to adjacent soft tissues
Air	hyperechoic artefact
Air – mucosa interface	bright hyperechoic linear structure

Ultrasound of the airway[33,34]

Quick evaluation of airway can be done by Ultrasound imaging which is superior to clinical examination. It can be of great value and rampantly being used in operating theatre, critical care units and emergency units.[4] Precise elucidation of ultrasound images requires expertise.

Table 3 : Ultrasound imaging of different airway structures[43]

STRUCTURE	APPEARANCE
Tongue	Visualized deep to muscles of floor of mouth as curvilinear hyperechoic structure (on transverse view in submandibular region)
Muscles of tongue:	
➢ Myelohyoid and geniohyoid	Linear hypoechoic bands extending between mandible and hyoid (on sagittal view)
➢ Genioglossus and hyoglossus	Fan like hypoechoic structures
Lingual septum	Linear hyperechoic structure in midline
Dorsal surface of tongue	curvilinear hyperechoic structure due to air mucosal interface
Epiglottis	Curvilinear hypoechoic structure (inverted C). The identification of epiglottis in real time the recognition of epiglottis is hastened by tongue protrusion and swallowing manoeuvre and appears as separate moving structure inferior to base of tongue.

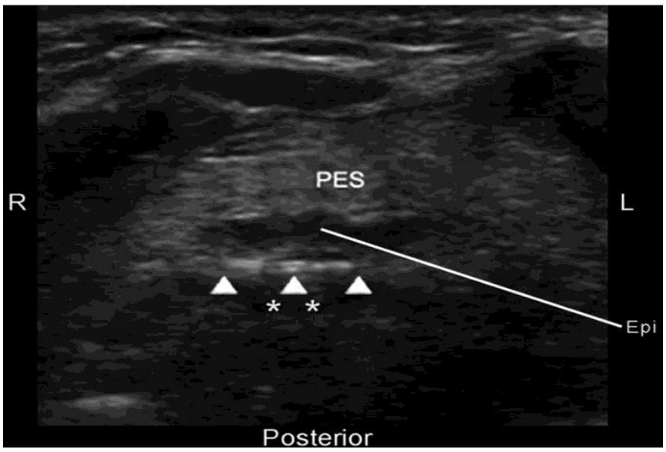


Figure 4 : USG image showing TS of Epiglottis in midline

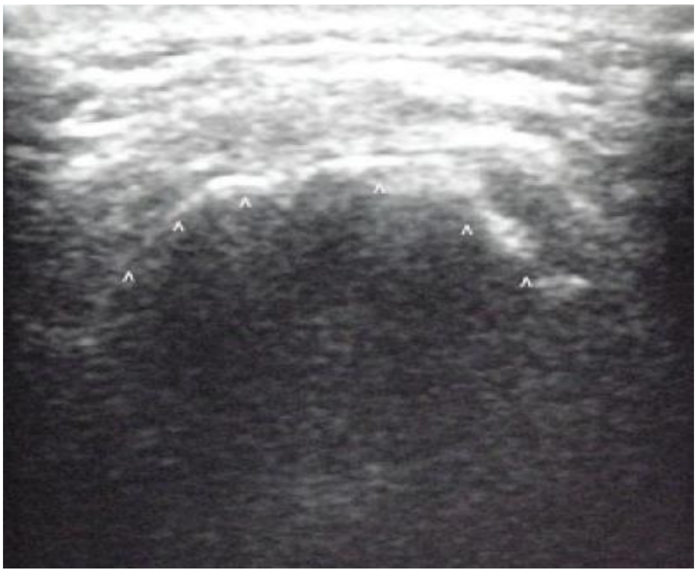


Figure 5 : USG image showing TS of hyoid bone in midline

STRUCTURE	APPEARANCE
Hyoid bone	Hyperechoic inverted U shaped structure with posterior acoustic shadowing (on transverse view) Narrow hyperechoic structure with an acoustic shadow (on sagittal and parasagittal view)
Thyrohyoid membrane	it provides sonographic window for visualization of epiglottis (on transverse and parasagittal view)
Cricoid cartilage and cricothyroid membrane	has an arch like appearance (on transverse view) posterior surface of anterior wall is traced by bright air mucosa interface as well as reverberation artifact called comet tail artifacts from intraluminal air round structure with hypoechoic appearance (parasagittal view)
False vocal cords	lie cephalad to true vocal cords and are hyperechoic in appearance, remain immobile during phonation
Trachea	As hypoechoic inverted U highlighted by linear hyperechoic air mucosa interface and reverberation artefact posteriorly (on transverse view), appear hypoechoic and resemble “string of beads” (on sagittal and parasagittal view)

STRUCTURE	APPEARANCE
Thyroid gland	at level of suprasternal notch, two lobes of thyroid with isthmus can be seen anterolateral to trachea (in transverse view) which appears homogeneously hyperechoic
Oesophagus	Seen at level of suprasternal notch posterolateral to trachea. Swallowing helps to see peristaltic movement and identification of esophageal lumen

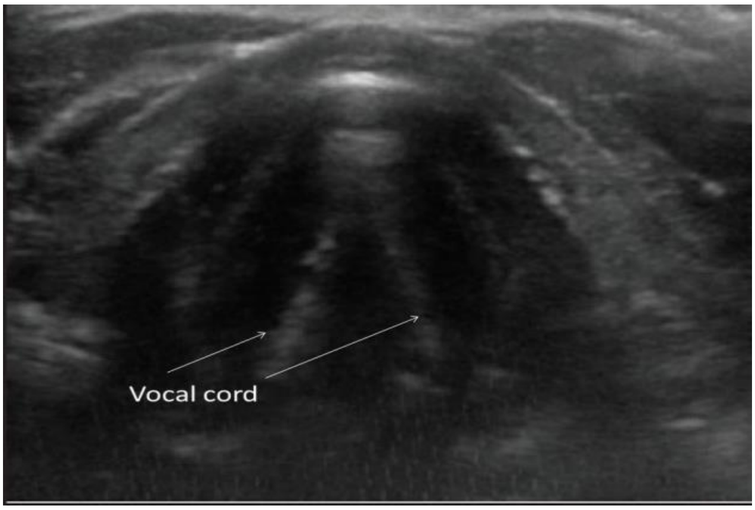


Figure 6: USG image showing TS of vocal cords in midline

<u>Clinical application of USG</u>[3,34,58]

- To foresee difficult airway: difficult laryngoscopy (Cormack-Lehane grade 3,4) corresponded ultrasonographic assessment of base of tongue, thickness of soft tissue. and distance of skin to anterior aspect of trachea.[59]
- Distance between upper border of hyoid and lower border of mentum (hyomental distance) is measured with head in neutral position and with hyperextension , ratio less than 1.1 implied difficult laryngoscopy. [58,60]
- Prandial status detection: Gastric contents can be quantified and detected prior to endotracheal intubation in emergency conditions .Consistency of the content can also be detected.
- Calculation of appropriate size of endotracheal, endobronchial and tracheostomy tube

- To confirm the position of ETT, laryngeal mask placement and gastric tube (Sengstaken -Blackmore tube) applied for severe oesophageal variceal bleeding. [27,58,62,67]
- Tracheostomy[63,64]: When surface landmarks are impalpable accurate localisation of trachea can be done by using ultrasound. Cannulation of trachea without perforating the posterior wall can be done by USG guidance in percutaneous dilatational tracheostomy
- To localise cricothyroid membrane in emergency cricothyrotomy [58,65]
- Airway related nerve blocks[58]: Awake fiber optic intubation can be performed under USG guided superior larynegeal nerve block in cases of difficult airway. The greater horn of hyoid and superior laryngeal artery can be identified and local anaesthetic can be injected in between
- To diagnose lung pathology[58,66]:
    a. USG prediction of pneumothorax is more sensitive and specific than chest X ray
    b. Lung sliding, B lines, lung pulse and lung point are characteristic of pneumothorax
    c. B lines are dynamic in diagnosing cardiogenic pulmonary oedema.
    d. In compression atelectasis, lung tissue is seen floating in pleural effusion called "jelly fish sign"
    e. Dark anechoic area between parietal and visceral pleura is seen in pleural effusion
    f. for which USG guided thoracentesis can be done.
    g. To diagnose pulmonary embolism
    h. Can be used to rule out other complications in patients with COPD
- Used in EFAST (extended focused assessment with sonography in trauma)
- To predict successful extubation[68]:Measurement of the breathing force of intubated patients receiving mechanical ventilation can be done by placing the probe on anterior axillary line on right and posterior axillary line on left for measurement of liver and spleen displacement in craniocaudal aspect respectively

Future aspects

- Pathology of larynx can be recognised by Endoscopic high frequency ultrasound: It has a thin catheter and a rotating mirror attached to high frequency probe, ultrasound rays are spread 360 degrees to produce image rectilinear to the catheter.
- Pathology of Acute dyspnoea can be ruled out using USG.

- USG is very handy in pregnancy to diagnose any lung pathology since radiation exposure has to be avoided.
- Pocket ultrasound and three dimensional ultrasound is evolving concept in the field of radio diagnosis.

METHODOLOGY

SOURCE OF DATA

This study was carried out in Department of Anesthesiology, B.L.D.E.U's Shri. B. M. Patil Medical College, Hospital and Research center, Vijayapura

METHOD OF COLLECTION OF DATA:

Study Design: A randomized comparative study

Study Period: one and half year from December 2018 to August 2020

Sample size

The anticipated mean ± SD of ETT size derived from height based formula and ETT size estimated by USG was 6.12±0.54 and 5.73±0.71 resp. [2]

The minimum sample size was 31 per group with 95% level of significance and 80% power.

Formula used:

$$N = 2\left[\frac{\left(Z_{1-(\propto/2} + z_{\beta}\right)\right) * S}{d}\right]^2$$

$Z_{1-\propto/2}$ Level of significance=95%

$Z_{1-\beta}$--power of the study=80%

d=clinically significant difference between two parameters

S= Common standard deviation

STATISTICAL METHODS:

- Data was represented using Mean ±SD, percentages and diagrams
- ANOVA test/Kruskal walli's test and Post hoc test were used to compare different groups.

- Significant difference between Qualitative data was found using Chi square or Fisher's Exact test if necessary

Randomization: The study population of 93 with age and sex matched was randomly selected and divided by computer generated random number table into 3 groups with 31 patients in each group

Group A: ETT size was calculated using age based formula

Group B:ETT size was calculated using height based formula

Group C: ETT size was calculated based on ultrasonographic measurements

Results was recorded using a preset performa

STUDY POPULATION

This study was done in paediatric patients undergoing various elective surgical procedures (ASA I and II) under general anaesthesia .

INCLUSION CRITERIA:

- Paediatric patients between 5-12 yrs of age
- Paediatric patients posted for elective surgeries under general anaesthesia (ASA I and II)
- Both male and female patients

EXCLUSION CRITERIA

- Inability to consent for the procedure
- Paediatric patients posted for emergency surgery under general anaesthesia
- Local infection of neck
- Burns and swellings in neck region
- Previous surgeries in neck
- Patients with anticipated difficult airway

PREANAESTHETIC EVALUATION:

Preanasesthetic evaluation in the study group included the following:

History:

History of underlying medical illness, previous history of surgery, anaesthetic exposure and hospitalization elicited

Physical examination:

General condition of patient

Vital signs -heart rate, blood pressure, respiratory rate

Height and weight

Airway assessement by Mallampatti grading

Examination of respiratory system, cardio vascular system, central nervous system and the vertebral system.

Procedure was explained to the patient and patient attenders.

Investigations /interventions:

Routine investigations which included CBC, HIV, HbsAg, Urine routine

Procedure:

Informed consent was taken from the patient attenders

Patients was kept nil by mouth 6 hrs before surgery

After shifting the patient to pre operative room

In group A: ETT size was calculated by Cole s age based formula

(ETT ID in mm=age/4+4)

In group B: ETT size was calculated by height based formula

(ETT ID in mm=height in cm /30+2). The height of the child was measured by a standard measuring tape (in cm) on a level surface against an even wall.

In group C: ETT size was calculated by ultrasonographic estimation of subglottic diameter (ETT OD in mm=subglotiic diameter in mm)

Technique of ultrasound

- Patient was positioned with head extended and neck flexed, USG probe positioned in the midline of neck.
- Patients was advised to take deep breath and hold the breath when asked, for 5 seconds to minimize respiratory induced changes in the measurement of upper airway.
- Subglottic diameter was estimated using USG linear probe (Sonosite M-Turbo machine) in B mode.
- The entire procedure took about 30 seconds.
- Ultrasonography began with localization of true vocal cords, seen as paired hyperechoic linear structures with respiratory and swallowing mobility, then probe was moved caudally to visualize cricoid arch.
- Transverse air column diameter was measured at cephalic half of cricoids cartilage. The measured subglottic diameter corresponded to the outer diameter(in mm) of the ETT tube to be used.

Table 4 : Internal and external diameter of the various ETT used

ETT size (internal diameter)	Outer diameter of tube
4.5	6mm
5	6.7mm
5.5	7.5mm
6	8.2mm
6.5	8.7mm
7	9.3mm

Figure 7: Sonosite Machine with Linear Transducer

- Patient was taken to the operation theatre, standard monitoring devices including pulse oximeter, sphygmomanometer cuff, $ETCO_2$, ECG leads were connected and baseline values were recorded.
- Iv line was secured with 22G cannula and patient was premedicated with Inj ondenstron 0.15mg/kg IV, Inj glycopyrolate 0.01mg/kg IV and Inj Midazolam 0.1mg/kg IV.
- Pre oxygenation was done with 100% oxygen for 3 minutes
- General anaesthesia was induced with propofol(2mg/kg) and muscle relaxation achieved by atracurium to facilitate the endotracheal intubation by direct laryngoscopy.
- The predetermined sized endotracheal tube was used.

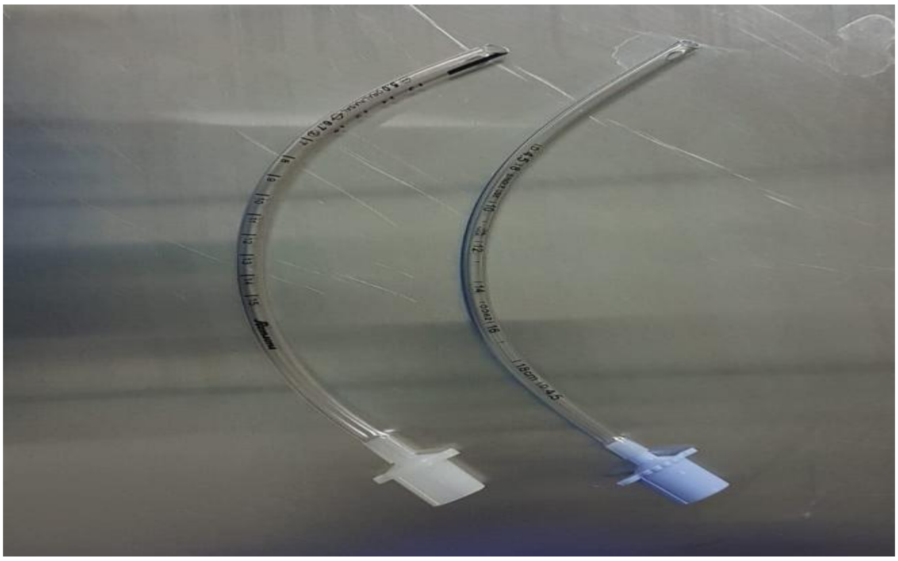


Figure 8: Uncuffed endotracheal tubes

- Endotracheal tube size was considered optimal when the tracheal leak is detected at inflation pressure of 10-20cm H_2O.
- If resistance was felt to ET tube passage into trachea or there is no audible leak when the lung is inflated to a pressure of 20-30cm H_2O, the tube was considered oversized and was exchanged with 0.5mm smaller tube.
- But if leak occurs at an inflation pressure less than 10cm H_2O, then ETT was considered undersized and was exchanged with 0.5mm larger tube.
- Intra operatively the patient was monitored for associated complications such as a)inadequate ventilation which will reflect as poor chest expansion, absent or quiet breath sounds, absent or poor end tidal CO_2 trace fall in oxygen saturation b)aspiration which was identified by recognition of gastric contents in oropharynx or airway, hypoxia, high airway pressures and coarse creptitations on auscultation of chest and it was managed by giving head low position ,through oral and endotracheal tube suctioning prior to application of positive pressure ventilation, administration of IV corticosteroids and IV antibiotic
- Post extubation the patient was monitored for laryngospasm which will present as fall in saturation and stridor for which 100% oxygen will be provided, iv corticosteroids was given and if required sub optimal dose of inj succinylcholine was given. In case of persistant laryngospasm the patient was reintubated .

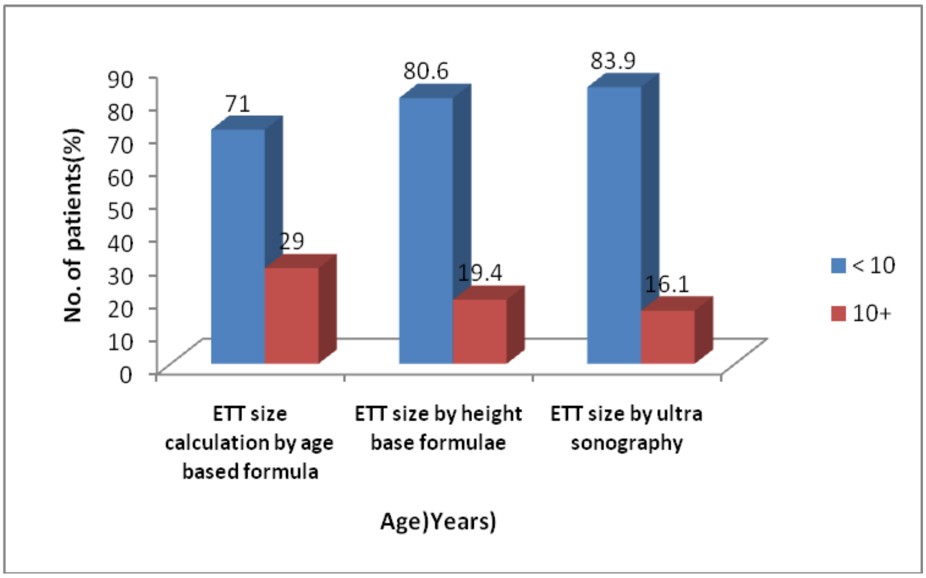
OBSERVATIONS AND RESULTS

Table 5: Distribution of patients according to age (years)

Age (years)	Group A ETT size estimation by age based formula		Group B ETT size estimation by height based formula		Group C ETT size estimation by ultrasonography		P value
	Frequency	Percent	Frequency	Percent	Frequency	Percent	
< 10	22	71.0	25	80.6	26	83.9	0.437
10+	9	29.0	6	19.4	5	16.1	
Total	31	100.0	31	100.0	31	100.0	
Mean± SD	7.1±2.49		7.74±2.64		7.61±2.48		

The association between age group among the three groups

- Mean age for Group A (Age based formula) participants is 7.1 ± 2.49.
- Mean age for Group B (Height based formula) participants is 7.74 ± 2.64.
- Mean age for Group C (Ultrasonography) participants is 7.61 ± 2.48.
- This data is statistically insignificant with P value 0.437

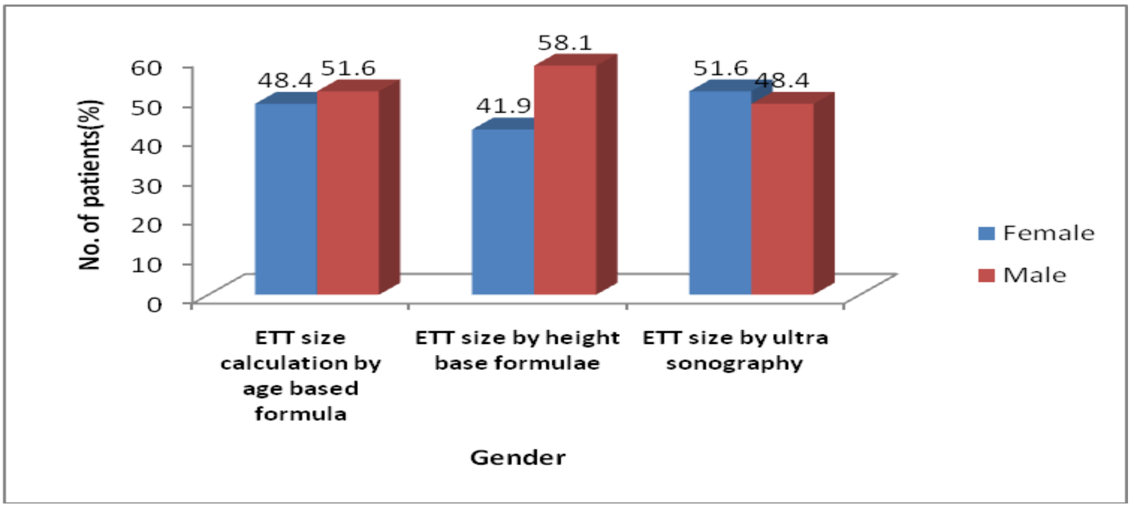


Graph 1: Proportion graph representing percentage of different age groups with respect to their percentage proportion among the three groups

Table 6: Distribution of patients according to gender

Gender	Group A ETT size estimation by age based formula		Group B ETT size estimation by height based formula		Group C ETT size estimation by Ultrasonography		Chi square Test	P value
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
Female	15	48.4	13	41.9	16	51.6	X^2= 0.639	0.7394
Male	16	51.6	18	58.1	15	48.4		
Total	31	100.0	31	100.0	31	100.0		

- Out of 93 participants, in Group A 16 patients were males and 15 patients were females, in Group B 18 patients were males and 13 patients were females and in Group C 15 patients were males and 16 patients were females.
- P values of gender was 0.7394 which was statistically insignificant
- It is found that there is no significant association between age and gender among the three groups. Hence age and sex are not confounding factors in the study

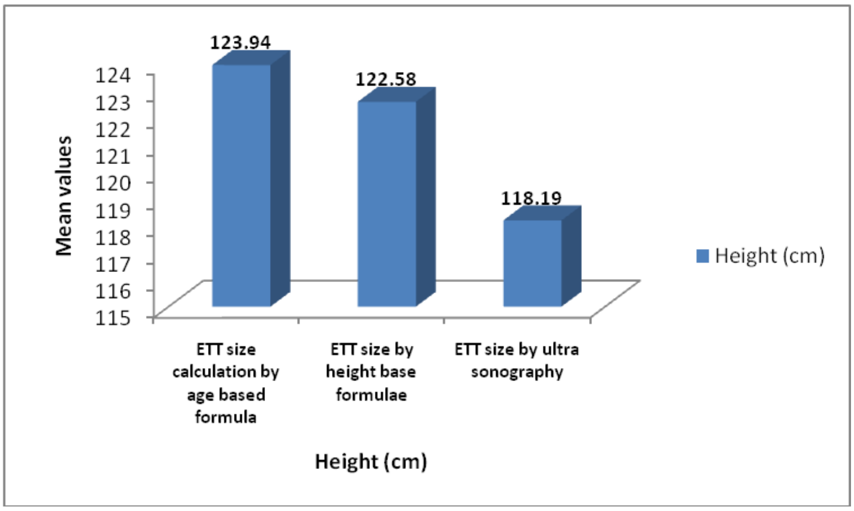


Graph 2: Graph representing percentage gender distribution among the three groups

Table 7: Distribution of patients according to height

Variables	Group A ETT size estimation by age based formula	Group B ETT size estimation by height based formula	Group C ETT size estimation by ultrasonography	Kruskal Wallis test	P value
	Mean±SD	Mean±SD	Mean±SD		
Height (cm)	123.94±15.786	122.58±14.146	118.19±11.02	KW=2.449	0.294

- Mean height for Group A(Age based formula) participants is 123.94±15.786
- Mean height for Group B (Height based formula) participants is 122.58±14.146
- Mean height for Group C (Ultrasonography) participants is 118.19±11.02
- The data obtained was statistically insignificant with P value 0.294, which means the three groups were comparable and randomized properly

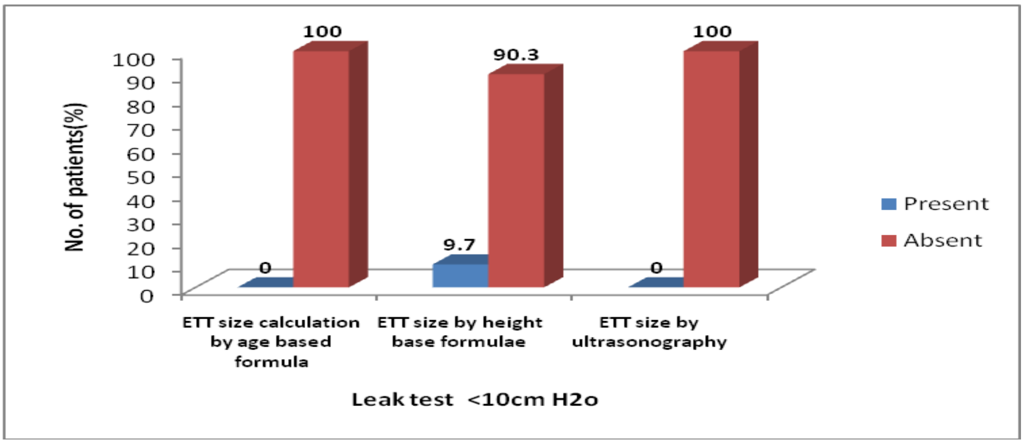


Graph 3: Graph representing height distribution among the three groups

Table 8: Distribution of patients according to leak test--<10cm H_2O

Leak at- <10cm H_2O	Group A ETT size estimation by age based formula		Group B ETT size estimation by height base formula		Group C ETT size estimation by ultrasonography		Chi square test	P value
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
Present	0	0	3	9.7	0	0	X^2=6.200	0.0450
Absent	31	100.0	28	90.3	31	100.0		
Total	31	100.0	31	100.0	31	100.0		

- If leak occurred at an inflation pressure of <10cmH_2O then the tube was considered under sized
- In Group A (ETT size by age based formula) leak test at <10 cm H_2O was not positive in any of the patients
- In Group B (ETT size by height based formula) leak test at <10cm H_2O was positive in 3 patients (9.7%)
- In Group C (ETT size by ultrasonography) leak test at <10cm H_2O was not positive in any of the patients
- This data was statistically significant with P value 0.0450

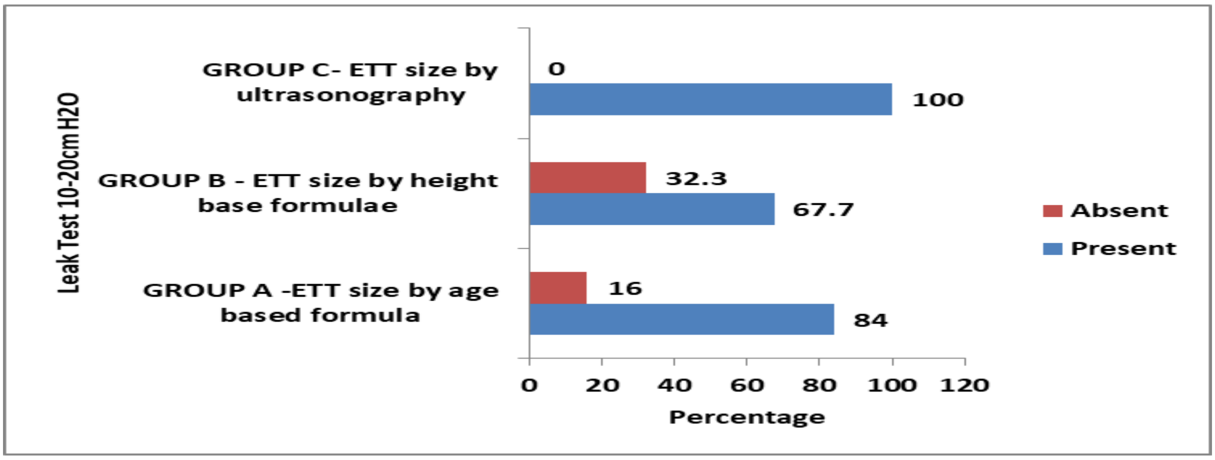


Graph 4: Graph representing percentage positivity of leak test at <10 cm H_2O among the three groups

Table 9: Distribution of patients according to leak test 10-20cm H_2O

Leak test 10-20cm H_2O	Group A ETT size estimation by age based formula		Group B ETT size estimation by height based formula		Group C ETT size estimation by ultrasonography		Chi square test	P value
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
Present	26	84	21	67.7	31	0	X^2=49.124	<0.0001
Absent	5	16	10	32.3	0	100.0		
Total	31	100.0	31	100.0	31	100.0		

- If leak occurred at an inflation pressure of 10-20cmH_2O then the tube was considered appropriate
- In Group A (ETT size by age based formula) leak test at 10-20cm H_2O was positive in 26 patients (84%) and negative in 5 patients (16%)
- In Group B (ETT size by height based formula) leak test at 10-20cm H_2O was positive in 21 patients (67.7%) and absent in 10 patients (32.3%)
- In Group C (ETT size by ultrasonography) leak test at 10-20cm H_2O was not positive in all 31 patients (100%)
- This data was statistically highly significant with P value <0.0001

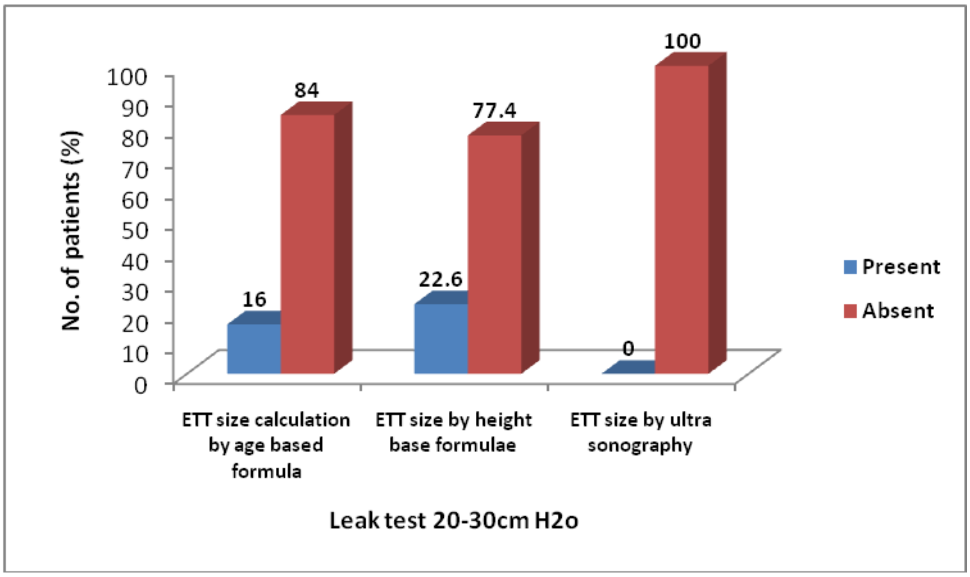


Graph 5: Graph representing percentage positivity of leak test at 10-20 cm H_2O among the three Groups

Table 10: Distribution of patients according to leak test 20-30cm H_2O

Leak test 20-30cm H_2O	Group A ETT size estimation by age based formula		Group B ETT size estimation by height based formula		Group C ETT size estimation by ultrasonography		Chi square test	P value
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
Present	5	16	7	22.6	0	0	X^2=7.463	0.0240
Absent	26	84	24	77.4	31	100		
Total	31	100.0	31	100.0	31	100.0		

- If leak occurred at an inflation pressure of 20-30 cmH_2O then the tube was considered oversized
- In group A (ETT size by age based formula) leak test at 20-30 cm H_2O was positive in 5 patients (16%)
- In group B (ETT size by height based formula) leak test at 20-30 cm H_2O was positive in 7 patients (22.6%)
- In group C (ETT size by ultrasonography) leak test at 20-30cm H_2O was not positive in any of the patients
- This data was statistically significant with P value 0.024

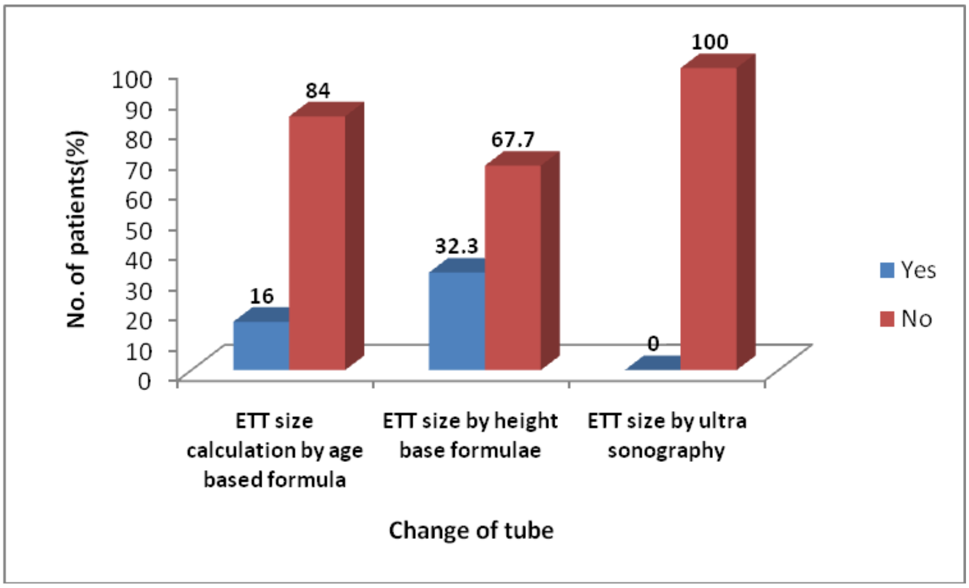


Graph 6: Graph representing percentage positivity of leak test at 20-30cm H_2O among the three groups

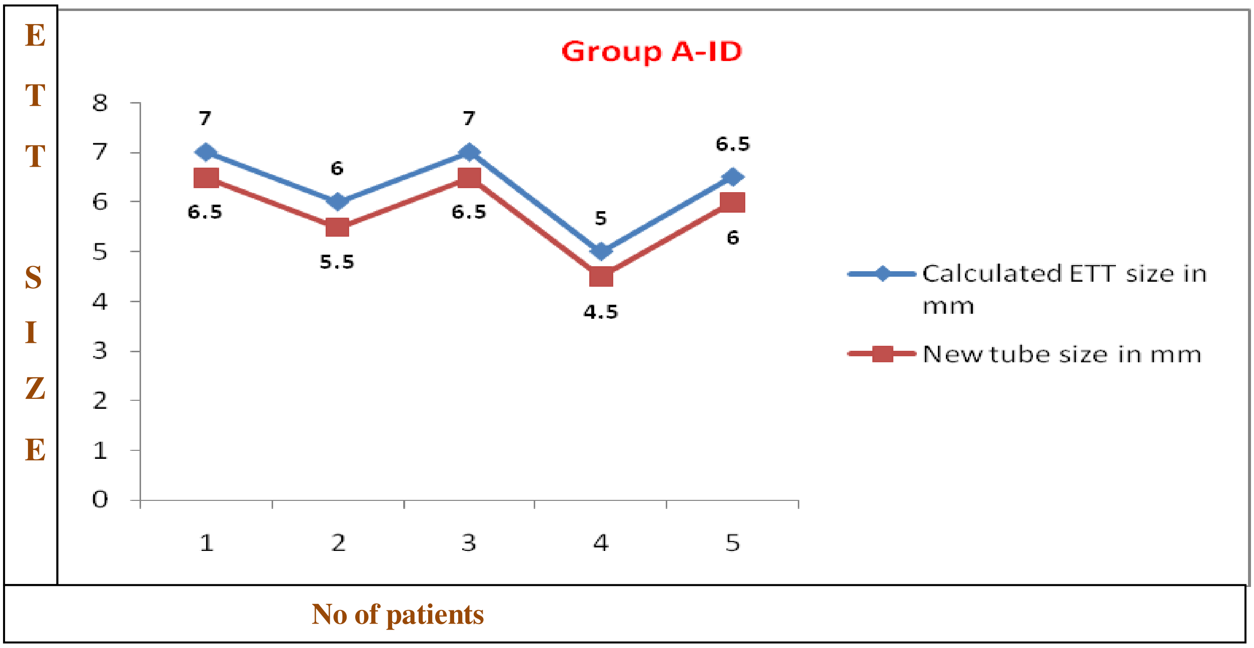
Table 11: Distribution of patients according to change of ETT

change of ETT	Group A ETT size estimation by age based formula		Group B ETT size estimation by height based formula		Group C ETT size estimation by ultrasonography		Chi square test	P value
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
Yes	5	16	10	32.3	0	0	X^2=11.923	0.0026
No	26	84	21	67.7	31	100		
Total	31	100.0	31	100.0	31	100.0		

- In Group A (ETT size by age based formula) tube was changed in 5 patients(16%) and was not changed in 26 patients (84%)
- In Group B (ETT size by height based formula) tube was changed in 10 patients (32.3%) and was not changed in 21 patients (67.7%)
- In Group C (ETT size by ultrasonography) tube was not changed in any patients (0%) and originally selected tube was used in all patients (100%)
- This data was statistically highly significant with P value 0.0026

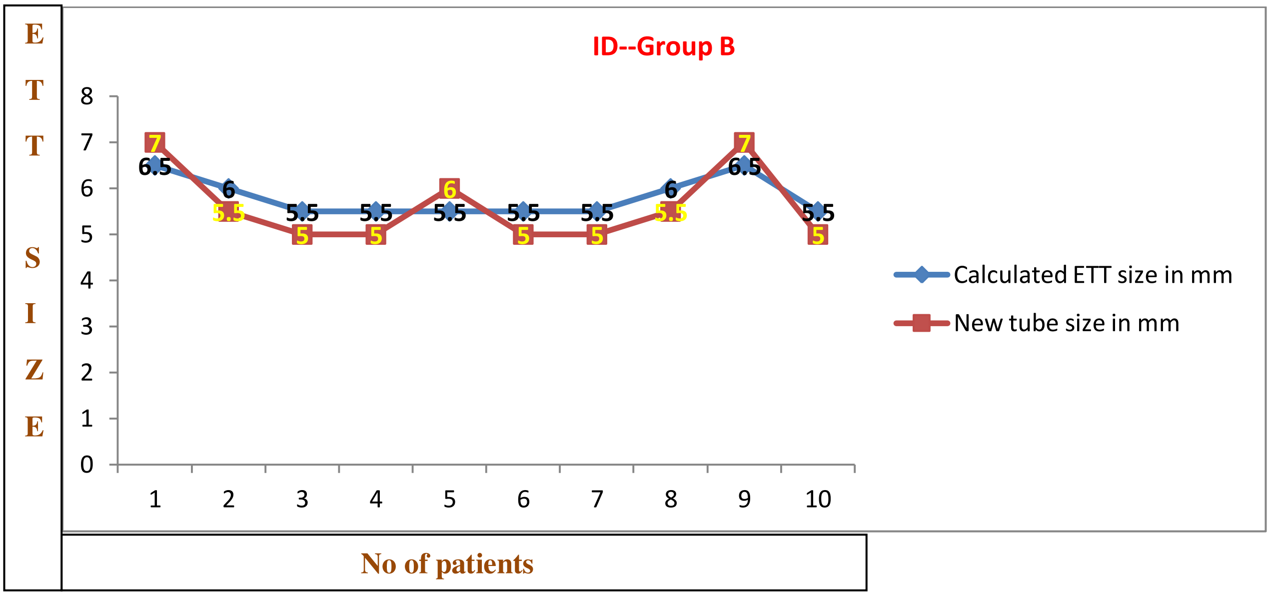


Graph 7: Representing percentage change of tube in each group



Graph 8: Comparison between calculated ETT size and new ETT size in Group A

- In group A change of tube was done in 5 patients
- The new ETT size used was one size small than the calculated ETT size in all the 5 patients
- It implies that age based formula over estimated ETT size in 5 patient



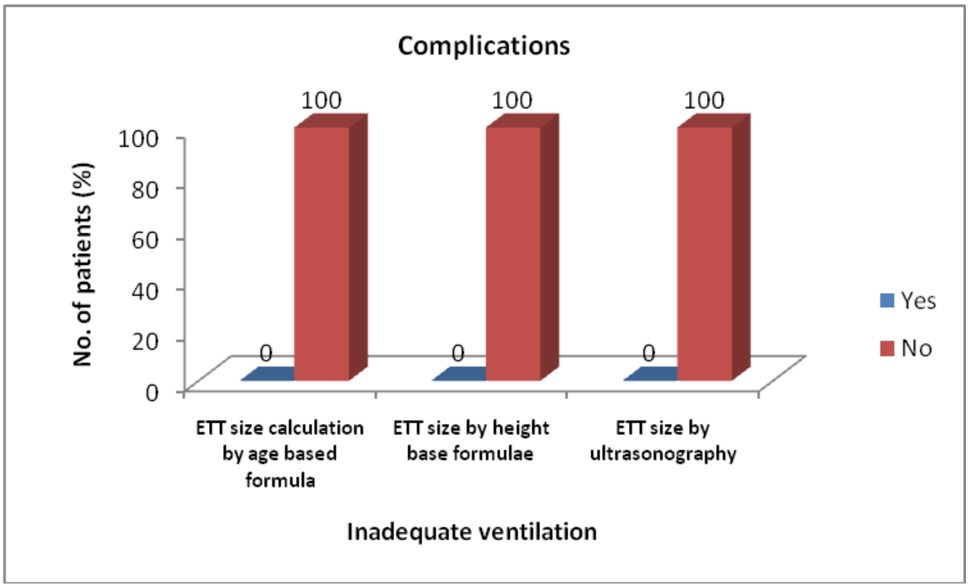
Graph 9: Comparison between calculated ETT size and new ETT size in Group B

- In group A change of tube was done in 10 patients
- The new ETT size used was one size small than the calculated ETT size in 7 patients and it was one size bigger than the calculated ETT size in 3 patients
- It implies that height based formula over estimated ETT size in 7 patient and underestimated the ETT size in 3 patients

Table 12: Distribution of patients according to complications- Inadequate ventilation

Inadequate Ventilation	Group A ETT size estimation by age based formula		Group B ETT size estimation by height based formula		Group C ETT size estimation by ultrasonography		Chi square test	P value
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
Yes	0	0	0	0	0	0	NA	
No	31	100.0	31	100.0	31	100		
Total	31	100.0	31	100.0	31	100.0		
NA:Not applicable								

- In Group A (ETT size by age based formula) inadequate ventilation was not seen in any of the patients (0%)
- In Group B (ETT size by height based formula) inadequate ventilation did not occur in any patients (0%)
- In Group C (ETT size by ultrasonography) inadequate ventilation was not seen in any patients (0%)
- Inadequate ventilation as complication was never encountered in any of the groups

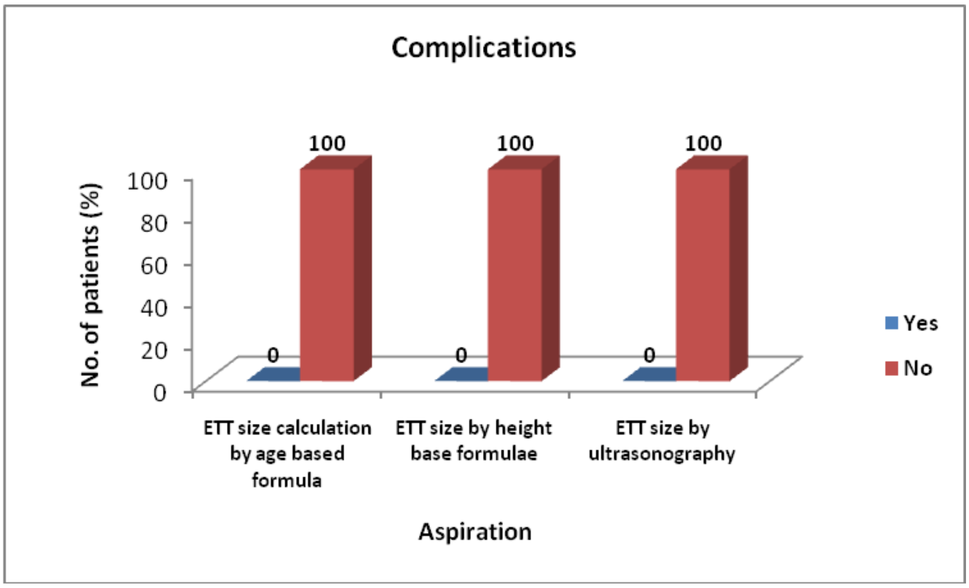


Graph 10: Diagrammatic representation of occurrence of inadequate ventilation among the three groups

Table 13: Distribution of patients according to complications- Aspiration

Aspiration	GROUP A -ETT size by age based formula		GROUP B - ETT size by height based formulae		GROUP C- ETT size by ultrasonography		Chi square test	P value
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
Yes	0	0	0	0	0	0	NA	
No	31	100.0	31	100.0	31	100.0		
Total	31	100.0	31	100.0	31	100.0		
NA: Not applicable								

- In Group A (ETT size by age based formula) aspiration was not seen in any of the patients (0%)
- In Group B (ETT size by height based formula) aspiration did not occur in any patients (0%)
- In Group C (ETT size by ultrasonography) aspiration was not seen in any patients (0%)
- Aspiration as complication was never encountered in any of the groups

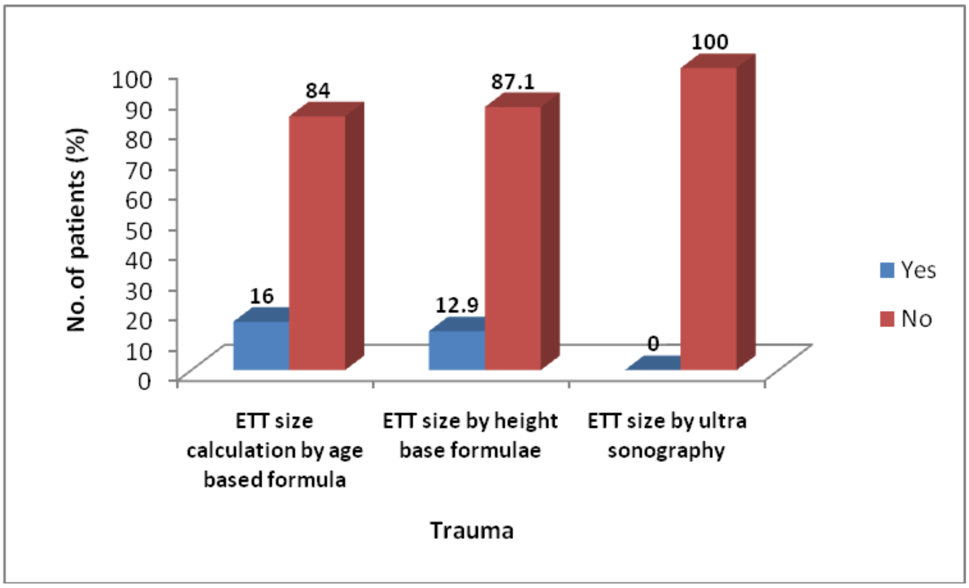


Graph 11: Diagrammatic representation of occurrence of aspiration among the three groups

Table 14: Distribution of patients according to complications- Trauma and bleeding

Trauma	Group A ETT size estimation by age based formula		Group B ETT size estimation by height based formula		Group C ETT size estimation by ultrasonography		Chi square test	P value
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
Yes	5	16	4	12.9	0	0	X^2=5.167	0.0755
No	26	84	27	87.1	31	100		
Total	31	100.0	31	100.0	31	100.0		

- In Group A (ETT size by age based formula) trauma was seen in 5 patients (16%)
- In Group B (ETT size by height based formula) trauma was seen in 4 patients (12.9%)
- In Group C (ETT size by ultrasonography) trauma was not seen in any patients (0%)
- Trauma was encountered in Group A and Group B which was statistically insignificant with P value 0.0755



Graph 12: Diagrammatic representation of occurrence of trauma among the 3 groups

STATISTICAL ANALYSIS

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean± standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square (χ^2) test was used for association between two categorical variables.

The formula for the chi-square statistic used in the chi square test is:

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

The subscript "c" are the degrees of freedom. "O" is observed value and E is expected value. C= (number of rows-1)* (number of columns-1)

The difference of the means of analysis variables between more than two independent groups was tested by Kruskal Wallis Test. The difference of the means of analysis variables between more than two independent groups was tested by Kruskal-Wallis H test. The Kruskal-Wallis H test is a rank-based nonparametric test that can be used to determine if there are statistically significant differences between two or more groups of an independent variable on a continuous or ordinal dependent variable.

Wilcoxon signed-rank test was used to compare paired observations. The Wilcoxon signed-rank test is a non-parametric statistical hypothesis test used to compare two related samples, matched samples, or repeated measurements on a single sample to assess whether their population mean ranks differ (i.e. it is a paired difference test).

DISCUSSION

Choosing appropriate size ETT is a salient aspect in paediatric anaesthesia for successful intubation. Intubation with a large sized tube may cause upper airway trauma leading to edema, laryngospasm and srtidor whereas intubation with a small sized tube may result in insufficient ventilation, increased risk of aspiration, leak of anaesthetic gas leading to poor end tidal gas monitoring and pollution of operating room environment. [1, 2, 3]

In paediatric age group the narrowest diameter of the upper airway is the subglottic region and it determines the size of endotracheal tube to be inserted. [3,4]

Estimation of suitable ETT size is done by several practices on which few studies have been conducted. Physical indices based calculation (age, height, weight) are used routinely for calculating ETT size whose accuracy is questionable .This leads to many complications and repeated laryngoscopies

Lakhal K et al (2007) conducted a study to measure the transverse diameter of subglottic area by using MRI and ultrasonography. They concluded that USG is a useful option in selecting appropriate ETT size in infants and children where cartilages are not calcified, more differences in airway dimensions are expected and correct ETT placement was crucial in them.[6] Hence in our study we compared the estimation of uncuffed ETT size by ultrasongraphy and the physical indices based formula (age and height) in paediatric patients

In our study the demographic data (age , sex, height) were comparable in all the three groups. The age group of the cases were ranging from 5-12 yrs with a mean of 7.1 ± 2.49 in Group A, 7.74 ± 2.64 in Group B and 7.61 ± 2.48 in Group C.

Out of 93 participants, in Group A 16 patients were males patients and 15 patients were females, in Group B 18 patients were males and 13 patients were females and in Group C 15 patients were males and 16 patients were females with P value of gender was 0.7394 .

The mean height of patients in Group A was 123.94, Group B was 122.58 and in Group C was 118.19 which was statistically insignificant

Thus the demographic data of all the three groups were not statistically significant which means that the groups were comparable and randomized properly.

In our study , in Group A ETT size was calculated by Cole s age based formula (ETT ID in mm=age/4+4) , in group B ETT size was calculated by height based formula(ETT ID in mm=height in cm /30+2) , In group C ETT size was calculated by ultrasonographic estimation of subglottic diameter (ETT OD in mm=subglotiic diameter in mm)

In the study conducted by Suominen P et al (2006) he concluded that two factors that significantly increased the post extubation complications were experience of anaesthetist less than 6 months and leak pressures at 25cm of H2O.Hence appropriate size ETT should be inserted in patients especially paediatric patients as large size tube with leak pressures at or above 25cm of H_2O may lead to post extubation complications.(5)

In our study we compared the positivity of leak test was test at different inflation pressures in all the three groups. If audible leak was found at <10 cm H_2O ETT was considered undersized, at 10-20cm H_2O leak ETT was considered optimal and at 20-30cm H_2O ETT was considered oversized.

At<10 cm H_2O : In Group A and Group C leak test was never positive, where as in Group B it was positive in 3(9.7%) patients which implies that ETT size was underestimated in 9.7% patients when height based formula was used

At 20-30 cm H_2O :In Group A leak test was positive in 5 patient (16%) , in Group B leak test was positive in 7 patients (22.6%) and in Group C it was never positive which implies that ETT size was overestimated in 16% patients when calculated by age based formula and 22.6% patients when calculated by height based formula .

At 10 – 20 cm H_2O : In Group A leak test was positive in 26 patients (84%) , in Group B leak test was positive in 21 patients (67.7%) and in Group C leak test was positive in 31 patients (100%)

This implies that ETT size was most accurately calculated in Group C where estimation was done by Ultrasonography (100%) followed by Group A where estimation was done by age based formula (84%) followed by Group B where estimation was done by height based formula (67.7%).

In our study the frequency of change of ETT due to inappropriate size were as follows:

In Group A change of ETT was done in 5 patients (16%).In all the 5 patients ETT size was overestimated and was replaced by one size smaller tube

In Group B change of tube was done in 10 patients (32.3%) among which in 3 patients ETT size was underestimated and was replaced by one size larger tube and in 7 patients ETT size was overestimated and was replaced by one size smaller tube.

In Group C change of tube was never done in any patients.

Sibasaki (2010) in his study concluded that suitable size ETT in paediatric patients can be chosen by utilizing USG to measure the subglottic airway diameter and was superior to age and height based formulas in calculating ETT size.[31]Our study results were comparable to their findings.

Gupta K (2012) compared size of clinically used ETT with size estimated using USG and age based formula. They did not find any difference between age based formulae and ultrasound measured diameters in 3-6 age group. But there was a higher rate of success of selecting the correct size of ETT when using ultra sound in the higher age group (6-18years). He concluded his study by stating there was strong co relation between clinically used ETT size and that calculated by USG than that calculated by age based formula.[3] In our study also USG estimated the ETT size more accurately than the physical indices formula based method specifically for uncuffed tubes in paediatric age group.

Bae J-Y et al (2011) conducted a study on to determine the usefulness of ultrasonograpghy in selecting the correct uncuffed endotracheal tube in paediatric patients. In this after induction and paralysis of the patients, transverse subglottic diameter was measured using ultrasonography. Accoring to which Ultrasonography determined tube size resulted in correct tube placement in 60 out of 100 patients (60%). Age based formula Resulted in correct tube selection in 31% only.[8] However in our study USG was done in pre anaesthetic room as our study group was between 5-12 years and the patients were co-operative.

Sutagatti JG, Raja R, Kurdi MS (2017) conducted a study in which comparision of clinically estimated tube size was done with, tube size determined by USG and that which was calculated by height and age. Among the three USG was concluded to be the best followed by age based formula. Correlation was not found between the size predicted by height based formula and clinically used tube.[2] Here like in our study 3 different methods of calculation were compared but in contrast to our study both cuffed and uncuffed tubes were used in this study.

In our study we compared the complications which occurred till post extubation period in all the three groups.

Trauma and bleeding were seen in 5 patients (16%) in Group A , 4 patients(12.9%) in Group B and it was not seen in Group C.

Aspiration and inadequate ventilation were not seen in any of the groups

The limitation of our study was that Air leak test was a subjective estimate and was affected by factors like position of the head and degree of neuromuscular blockade.

As in contrast to CT and MRI, performing USG does not demand strict immobilization especially in paediatric age group.(6) However USG relys on the skill of the operator which demands training , still doesn’t have a steep learning curve.

CONCLUSION

USG is portable device, with no radiation exposure, quick and gives real time dynamic images which can be very handy in many emergency and elective situations. Our study shows the prospective use of USG for estimation of ETT size of uncuffed tubes. Estimation of uncuffed ETT size was most accurate with ultrasonography than compared to age based formula or height based formula.

Complication like bleeding and trauma was not seen in the ultrasonography group which were seen in the other two groups

Hence we concluded that Ultasonography is a better tool for measuring uncuffed ETT size than the physical indices based formula method in paediatric patients posted for surgery under general anaesthesia.

SUMMARY

This randomised comparative study titled "**ESTIMATION OF ENDOTRACHEAL TUBE SIZE BY THE PHYSICAL INDICES BASED FORMULAE VERSUS ULTRASONOGRAPHY IN PEDIATRIC PATIENTS POSTED FOR SURGERY UNDER GENERAL ANAESTHESIA**" was carried out from December 2018 to august 2020 in the department of anaesthesiology at B.L.D.E (Deemed To Be University) Shri. B. M. Patil Medical College and Hospital, Vijayapur.

The study was designed to compare Ultrasonograpy with physical indices(age and height) based formula for estimation of uncuffed endotracheal tube size in paediatric patients planned for procedures under general anaesthesia. The following parameters were considered:

Leak test positivity at different inflation pressures (<10cm H_2O ,10-20cm H_2O ,30-40cm H_2O), frequency of change of tube and the associated complications

The study population of 93 with age and sex matched was randomly selected and divided by computer generated random number tables in to three groups with 31 patients between the age of 5 years to 12 years of ASA grade I and II in each group:

Group A: ET tube size was calculated using age based formula

Group B: ET tube size will be calculated using height based formula

Group C: ET tube size will be calculated based on ultrasonographic measurements

The observations and results were analysed statistically and were as follows: The demographic data of all the three groups were not statistically significant; meaning all the groups were comparable and randomised properly.

Leak test positivity at <10cm H_2O was seen in group B and not seen in Group A or Group C which meant underestimation of ETT size was seen with height based formula

Leak test positivity at 20-30 cm H_2O was seen in Group A and Group B and was not seen in group C which meant overestimation of ETT size was seen in Group A and Group B

Leak test positivity at 10-20 cm H_2O was seen in all the patient in Group C and comparatively the number was less in Group B and Group C which meant ultrasonographic estimated ETT size accurately

Frequency of change of ETT was the more in Group B followed by Group A and not seen in Group C

Complications or side effects: In our study we noted that the complications or side effects were noted in Group A and Group B and were not seen in Group C

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ANNEXURE I:

ETHICAL COMMITTE CLEARANCE CERTIFICATE

B.L.D.E (Deemed to be University)
SHRI.B.M.PATIL MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE
VIJAYAPUR – 586103

IEC/NO: 286/2018
17-11-2018

INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 13-11-2018 at 03-15 PM scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has accorded Ethical Clearance.

Title : Estimation of endotracheal tube size by the physical indices based formulae versus ultrasonography in pediatric patients posted for surgery under general Anaesthesia: A randomized comparative study.

Name of P.G. Student : Dr Arpitha.C..
Department of General Anaesthesiology

Name of Guide/Co-investigator: Dr. Sridevi Mulimani, Associate Professor of Anaesthesiology.

DR RAGHAVENDRA KULKARNI
CHAIRMAN
Institutional Ethical Committee
BLDEU's Shri B.M. Patil
Medical College,BIJAPUR-586103.

Following documents were placed before E.C. for Scrutinization:

1) Copy of Synopsis/Research Project
2) Copy of informed consent form.
3) Any other relevant documents

B.L.D.E.Us, SHRI.B.M.PATIL MEDICAL COLLEGE, VIJAYAPUR – 586103

INSTITUTIONAL ETHICAL COMMITTEE, **Date :** 13-11-18

1. Name of UG/PG Student/Researcher : Dr Aparna C.
2. Department : Anaesthesiology
3. Title : Estimation .... – comparative study
4. Guide/Co-Guide/Principal Researcher : Dr Sridevi Mulimani
5. Date of Admission (PG Only) : May 2018

Charges ...

Earlier charges were collected or not is to be informed.

I.E.C. Remarks: Ethical clearance accorded/be chairman after corrected revised version and approval.

2. Any adverse effects to subject of the study should be intimated in writing to E.C.
3. If study is stopped or an included patient is out of study inform E.C. the same with reason.

Signature of the Committee Members:

2. DR TEJASWINI VALLABHA —[signature]—

[redacted]

5. DR CHANDRASHEKHAR ...

ANNXURE II

INFORMED CONSENT FORM

B.L.D.E.U.'s SHRI B.M.PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTER, VIJAYAPURA - 586103, KARNATAKA

TITLE OF THE PROJECT: ESTIMATION OF ENDOTRACHEAL TUBE SIZE BY THE PHYSICAL INDICES BASED FORMULAE VERSUS ULTRASONOGRAPHY IN PEDIATRIC PATIENTS POSTED FOR SURGERY UNDER GENERAL ANAESTHESIA: A RANDOMIZED COMPARATIVE STUDY

PRINCIPAL INVESTIGATOR: Dr. ARPITHA .C
Department of Anaesthesiology
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E mail: arpitha439@gmail.com

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M.D ANAESTHESIOLOGY
Associate Professor
Dept of Anaesthesiology
BLDE University's Shri B M Patil Medical College &
Research Center, Sholapur Road Vijayapura-03

PURPOSE OF RESEARCH:

I have been informed that this study is Estimation of endotracheal tube size by the physical indices based formulae versus ultrasonography in pediatric patients posted for surgery under general anaesthesia: A Randomized Comparative Study. I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice of either being included or not in the study.

PROCEDURE:

I understand that I will be participating in the study Estimation of endotracheal tube size by the physical indices based formulae versus ultrasonography in pediatric patients posted for surgery under general anaesthesia: A Randomized Comparative Study

RISKS AND DISCOMFORTS:

I understand that my ward may experience some discomfort during the procedure and I understand that necessary measures will be taken to reduce them

BENEFITS:

I understand that my ward participating in this study will help in finding out Estimation of endotracheal tube size by the physical indices based formulae versus ultrasonography in pediatric patients posted for surgery under general anaesthesia: A Randomized Comparative Study

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this hospital records and will be subjected to the confidentiality and privacy regulation of this hospital.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identities such as photographs and audio and video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. Dr. ARPITHA. C is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study ,or later I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me. And that a copy of this consent form will be given to me for keep for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand Dr. ARPITHA.C will terminate my participation in this study at any time after she has explained the reason for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely events of injury to me/my ward, resulting directly due to my participation in this study, such injury will be reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving my legal rights. I have explained to____ the purpose of this research , the procedure required and the possible risk and benefits, to the best of my ability in patients own language

DATE   Dr. ARPITHA. C (investigator)

PATIENT/PARENT SIGNATURE   Witness

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. ARPITHA.C has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I inderstand the same. Therefore I agree to give my consent to participate as a subject in this research project.

______________________ _______________

(Participant) (Date)

________________________ ________________

(Witness to above signature)

ANNEXURE III

CASE PROFORMA

STUDY: ESTIMATION OF ENDOTRACHEAL TUBE SIZE BY THE PHYSICAL INDICES BASED FORMULAE VERSUS ULTRASONOGRAPHY IN PEDIATRIC PATIENTS POSTED FOR SURGERY UNDER GENERAL ANAESTHESIA: A RANDOMIZED COMPARATIVE STUDY

Patient Details

Name Age Sex Height weight

Ward Group allotted by randomization:I/II/III

Diagnosis

Surgical procedure

Past history

General physical examination:

Pallour ictreus cyanosis clubbing lymphadenopathy edema

Mallampatti Grade:

Vital parameters:

Pulse blood pressure respiratory rate temperature

Systemic Examination

CVS

RS

CNS

PA

Investigations

Haemoglobin: TLC: Platelet count:

Urine routine: HIV: HbsAg:

ASA grade

Parameters:

METHOD USED	GROUP A Age based ETT ID in mm=age/4+4	GROUP B Height based ETT ID in mm=height in cm /30+2	GROUP C Ultrasound estimation Subglottic diameter in mm=ETT OD in mm
Calculated ETT size			
OD			
ID			
Size of ETT used during surgery(ID)			
Leak test			
>10cm H2O			
10-20cmH2O			
20-30cmH2O			
Change of tube Y/N			
New tube size			

COMPLICATIONS

METHOD USED	GROUP A	GROUP B	GROUP C
Inadequate ventilation			
Aspiration			
Other complications			

GROUP A -ETT SIZE CALCULATION BY AGE BASED FORMULA

(ETT ID in mm=age/4+4)

Sl no	patient name	age	sex	height	calculated ett size in mm		leak test			change of tube	new tube size in mm		complications		
					ID	ED	>10cm H2o	10-20cm H2o	20-30cm H2o		ID	ED	inadequate ventilation	aspiration	trauma
1	Bhagat	7yrs	male	120cm	5.5	7.5	-	present	-	no	-	-	no	no	no
2	Sakshi	6yrs	female	124 cm	5.5	7.5	-	present	-	no	-	-	no	no	no
3	Samarth	5yrs	male	110cm	5	6.7	-	present	-	no	-	-	no	no	no
4	pranav	5yrs	male	112cm	5	6.7	-	present	-	no	-	-	no	no	no
5	Ishwar	12yrs	male	150cm	7	9.3	-	-	present	yes	6.5	8.7	no	no	yes
6	prathiba	11yrs	female	144cm	6.5	8.7	-	present	-	no	-	-	no	no	no
7	saikumar	5yrs	male	108cm	5	6.7	-	present	-	no	-	-	no	no	no
8	laxmi	8yrs	female	118cm	6	8.2	-	-	present	yes	5.5	7.5	no	no	yes
9	rahul	8yrs	male	128cm	6	8.2	-	present	-	no	-	-	no	no	no
10	pradeep	5ys	male	104cm	5	6.7	-	present	-	no	-	-	no	no	no
11	vasai	8yrs	female	112cm	6	8.2	-	present	-	no	-	-	no	no	no
12	pooja	9yrs	female	144cm	6	8.2	-	present	-	no	-	-	no	no	no
13	basavraj	12yrs	male	148cm	7	9.3	-	-	present	yes	6.5	8.7	no	no	yes
14	akash	12yrs	male	154cm	7	9.3	-	present	-	no	-	-	no	no	no
15	roopa	5yrs	female	104cm	5	6.7	-	present	-	no	-	-	no	no	no
16	rakesh	10yrs	male	140cm	6.5	8.7	-	present	-	no	-	-	no	no	no
17	shivaraj	10yrs	male	150cm	6.5	8.7	-	present	-	no	-	-	no	no	no
18	prathiba	5yrs	female	111cm	5	6.7	-	present	-	no	-	-	no	no	no
19	renuka	7yrs	female	115cm	5.5	7.5	-	present	-	no	-	-	no	no	no
20	suman	6yrs	female	120cm	5.5	7.5	-	present	-	no	-	-	no	no	no
21	sulagawwa	11yrs	female	130cm	6.5	8.7	-	present	-	no	-	-	no	no	no
22	sahana	7yrs	female	120cm	5.5	7.5	-	present	-	no	-	-	no	no	no
23	shivaram	7yrs	male	130cm	5.5	7.5	-	present	-	no	-	-	no	no	no
24	mahesh	6yrs	male	110cm	5.5	7.5	-	present	-	no	-	-	no	no	no
25	roopashree	5yrs	female	110cm	5	6.7	-	present	-	no	-	-	no	no	no
26	veeresh	6yrs	male	110cm	5.5	7.5	-	present	-	no	-	-	no	no	no
27	malamma	7yrs	female	120cm	5.5	7.5	-	present	-	no	-	-	no	no	no
28	akamma	5yrs	female	109cm	5	6.7	-	-	present	yes	4.5	6	no	no	yes
29	radha	10yrs	female	140cm	6.5	8.7	-	-	present	yes	6	8.2	no	no	yes
30	nandish	11yrs	male	140cm	6.5	8.7	-	present	-	no	-	-	no	no	no
31	shivanand	5yrs	male	107cm	5		-	present	-	no	-	-	no	no	no

GROUP B- Estimation of ETT size by height based formula

(ETT ID in mm=height in cm /30+2)

Sl no	patient name	age	sex	height	calculated ett size in mm		leak test			change of tube	new tube size in mm		complications		
					ID	ED	>10cm H2o	10-20cm H2o	20-30cm H2o		ID	ED	inadequate ventilation	aspiration	trauma
1	bharath	8yrs	male	130cm	6	8.2	-	present	-	no	-	-	no	no	no
2	vishwas	6yrs	male	126cm	6	8.2	-	present	-	no	-	-	no	no	no
3	arun	15yrs	male	160cm	7	9.3	-	present	-	no	-	-	no	no	no
4	pooja	9yrs	female	120cm	6	8.2	-	present	-	no	-	-	no	no	no
5	basavraj	12yrs	male	140cm	6.5	8.7	present	-	-	yes	7	9.3	no	no	no
6	shivraj	14yrs	male	160cm	7	9.3	-	present	-	no	-	-	no	no	no
7	shankar	7yrs	male	120cm	6	8.2	-	-	present	yes	5.5	7.5	no	no	yes
8	pavithra	10yrs	female	136cm	6.5	8.7	-	present	-	no	-	-	no	no	no
9	sunita	8yrs	female	120cm	6	8.2	-	present	-	no	-	-	no	no	no
10	radika	9yrs	female	122cm	6	8.2	-	present	-	no	-	-	no	no	no
11	shashank	5yrs	male	112cm	5.5	7.5	-	present	-	no	-	-	no	no	no
12	karthik	6yrs	male	114cm	5.5	7.5	-	present	-	no	-	-	no	no	no
13	raju	5yrs	male	106cm	5.5	7.5	-	-	present	yes	5	6.7	no	no	no
14	preethi	7yrs	female	120cm	6	8.2	-	present	-	no	-	-	no	no	no
15	swati	6yrs	female	104cm	5.5	7.5	-	present	-	no	-	-	no	no	no
16	raju	7yrs	male	116cm	5.5	7.5	-	present	-	no	-	-	no	no	no
17	shankar	8yrs	male	120cm	6	8.2	-	present	-	no	-	-	no	no	no
18	hema	5yrs	female	110cm	5.5	7.5	-	-	present	yes	5	6.7	no	no	yes
19	kishen	6yrs	male	117cm	5.5	7.5	-	present	-	no	-	-	no	no	no
20	shailesh	10yrs	male	148cm	6.5	8.7	-	present	-	no	-	-	no	no	no
21	shariq	6yrs	male	118cm	5.5	7.5	present	-	-	yes	6	8.2	no	no	no
22	malathi	5yrs	female	110cm	5.5	7.5	-	-	present	yes	5	6.7	no	no	yes
23	seema	7yrs	female	118cm	5.5	7.5	-	present	-	no	-	-	no	no	no
24	devaki	8yrs	female	120cm	6	8.2	-	present	-	no	-	-	no	no	no
25	sham	5yrs	male	108cm	5.5	7.5	-	-	present	yes	5	6.7	no	no	no
26	soumya	8yrs	female	122cm	6	8.2	-	present	-	no	-	-	no	no	no
27	madiya	7yrs	female	120cm	6	8.2	-	-	present	yes	5.5	7.5	no	no	yes
28	pratap	6yrs	male	114cm	5.5	7.5	-	present	-	no	-	-	no	no	no
29	geeta	8yrs	female	126cm	6	8.2	-	present	-	no	-	-	no	no	no
30	rakesh	12yrs	male	136cm	6.5	8.7	present	-	-	yes	7	9.3	no	no	no
31	pradeep	5yrs	male	107cm	5.5	7.5	-	-	present	yes	5	6.7	no	no	no

GROUP C -Estimation of ETT Size by ultrasonography

(Subglottic diameter in mm=ETT OD in mm)

Sl no	patient name	age	sex	height	calculated ett size in mm		leak test			change of tube	new tube size in mm		complications		
					ID	ED	>10cm H2o	10-20cm H2o	20-30cm H2o		ID	ED	inadequate ventilation	aspiration	trauma
1	abdul	5yrs	male	110cm	5	6.7	-	present	-	no	-	-	no	no	no
2	lakshmi	6yrs	female	116cm	5.5	7.5	-	present	-	no	-	-	no	no	no
3	ravi	8yrs	male	136cm	6.5	8.7	-	present	-	no	-	-	no	no	no
4	sindhu	10yrs	female	134cm	6.5	8.7	-	present	-	no	-	-	no	no	no
5	pradeep	5yrs	male	106cm	5	6.7	-	present	-	no	-	-	no	no	no
6	lakshmibai	7yrs	female	110cm	6	8.2	-	present	-	no	-	-	no	no	no
7	santosh	9yrs	male	130cm	6.5	8.7	-	present	-	no	-	-	no	no	no
8	suhas	6yrs	male	114cm	5	6.7	-	present	-	no	-	-	no	no	no
9	nikitha	5yrs	female	106cm	5	6.7	-	present	-	no	-	-	no	no	no
10	harshit	8yrs	male	130cm	6.5	8.7	-	present	-	no	-	-	no	no	no
11	navya	6yrs	female	112cm	5	6.7	-	present	-	no	-	-	no	no	no
12	geeta	6yrs	female	110cm	5.5	7.5	-	present	-	no	-	-	no	no	no
13	aarathi	10yrs	female	136cm	6.5	8.7	-	present	-	no	-	-	no	no	no
14	drishti	6yrs	female	112cm	5	6.7	-	present	-	no	-	-	no	no	no
15	vedanth	7yrs	male	120cm	5.5	7.5	-	present	-	no	-	-	no	no	no
16	malathi	5yrs	female	108cm	4.5	6	-	present	-	no	-	-	no	no	no
17	sarvesh	5yrs	male	110cm	5	6.7	-	present	-	no	-	-	no	no	no
18	veeresh	10yrs	male	130cm	6.5	8.7	-	present	-	no	-	-	no	no	no
19	leela	6yrs	female	112cm	5	6.7	-	present	-	no	-	-	no	no	no
20	swetha	5yrs	female	109cm	4.5	6	-	present	-	no	-	-	no	no	no
21	suma	8yrs	female	126cm	5.5	7.5	-	present	-	no	-	-	no	no	no
22	radha	5yrs	female	108cm	4.5	6	-	present	-	no	-	-	no	no	no
23	bharath	6yrs	male	116cm	5	6.7	-	present	-	no	-	-	no	no	no
24	basavaraj	9yrs	male	129cm	5.5	7.5	-	present	-	no	-	-	no	no	no
25	keerthana	5yrs	female	109cm	5	6.7	-	present	-	no	-	-	no	no	no
26	divya	7yrs	female	116cm	5.5	7.5	-	present	-	no	-	-	no	no	no
27	yuvraj	6yrs	male	112cm	5.5	7.5	-	present	-	no	-	-	no	no	no
28	revati	11yrs	female	130cm	6.5	8.7	-	present	-	no	-	-	no	no	no
29	harish	5yrs	male	111cm	4.5	6	-	present	-	no	-	-	no	no	no
30	kashinath	12yrs	male	146cm	6.5	8.7	-	present	-	no	-	-	no	no	no
31	akash	5yrs	male	110cm	5	6.7	-	present	-	no	-	-	no	no	no