"COMPARISION BETWEEN ULTRASOUND BASED TECHNIQUE AND AGE BASED FORMULA IN PREDICTION OF APPROPRIATE ENDOTRACHEAL TUBE SIZE IN CHILDREN –"ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY"

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"COMPARISON BETWEEN ULTRASOUND BASED TECHNIQUE AND AGE BASED FORMULA IN PREDICTION OF APPROPRIATE ENDOTRACHEAL TUBE SIZE IN CHILDREN – ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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ABSTRACT

Background - The most challenging task an anesthesiologists need to perform is in evaluation and securing of the paediatric airway. The aims of the study were to compare prediction of appropriate size endotracheal tube and the number of endo tracheal tube changes between age based formula and ultrasound based technique in children undergoing general anaesthesia.

Methods - 50 subjects of either gender aged between 1-8 years, undergoing various elective surgeries under general anaesthesia requiring endotracheal intubation were enrolled in the study. They were divided into two groups. In one group ETT size was estimated using traditional age based formula. In other group the ETT size was estimated by measuring transverse diameter at the level of cricoid cartilage by ultrasonography. The tracheal tube was considered appropriate if air leak was minimal at10-20 cm H_2O of airway pressure. The inter group continuous variables were compared using suitable tools of statistics like unpaired student's t test. Two quantitative variables, within a group, were compared using student's paired t test.

Results -The ETT measured in the ultrasonography group was more appropriate compared to age based formula group, the percentage of number of ETT changed was more in age based formula group, the results were significant (p-value 0.002).

Conclusion - In comparison to the conventional age-based formula, the ultrasound-based approach by measuring the subglottic diameter is a better, reliable, and non-invasive instrument in assessing the appropriate size of ETT in pediatric patients.

LIST OF ABBREVATION

1. B.P	=	Blood Pressure
2. R.R	=	Respiratory Rate
3. SPO2	=	Saturation
4. CNS	=	Central Nervous System
5. P/A	=	Per Abdomen
6. ASA	=	American Society of Anaesthesiologists
7. yrs	=	Years
8. kg	=	Kilogram
9. mg	=	milligram
10. ETI	=	Endotracheal Intubation
11. ETT	=	Endotracheal Tube
12. trans.	=	transverse
13. USG	=	Ultrasonography
14. no.	=	Number
15. SD	=	Subglottic Diameter
16. S.D	=	Standard deviation
17. Max	=	Maximun
18. AP	=	Anterio Posterior
19. ABF	=	Age Based Formula
20. GA	=	General Anaesthesia

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INTRODUCTION

Endotracheal intubation is routinely performed in neonates, infants and in children for various surgeries performed under General Anaesthesia. It is one of the most challenging procedure even for an senior anaesthesiologist.

Selection of endotracheal tube of an appropriate size is crucial step in paediatric patients because a tube of overtly large diameter may result in complications like, upper airway injury in the form of ulceration, ischemia, and scarring that may in turn lead to subglottic stenosis ,edema and post extubation stridor followed by respiratory compromise.[1] While an undersized tube can cause inappropriate ventilation, aspiration risk, increased gas flow resistance, inaccurate monitoring of end tidal gases. Reintubation may also be required occasionally with a different size of Endotracheal Tube.[2] Traditionally uncuffed tubes are used in children under 8 years irrespective of the indication and duration of intubation. Advantages of uncuffed ETT are lower resistance to air flow, larger internal diameter, Prevents increase in work of breathing, Allows easy suctioning, avoids trauma to subglottic region. Disadvantages of uncuffed ETT are leak around tube leading to unreliable monitoring of ventilatory parameters, need for high fresh gas flows, leading atmospheric pollution by anaesthetic gases which has economical implication and also health risk to operation theatre personnel. Hence the need to insert a proper size ETT.

Therefore it is very vital to determine the appropriate sized endotracheal tube in paediatric patients. The most commonly used method for determining the ideal endotracheal tube size is the age based namely [3,4] PENLINGTON formula:Age < 6 years- age/3 +3.5 = Internal Diameter (ID) of Endotracheal tube.Age > 6 years – age/4 +4.5= Internal Diameter (ID) of the Endotracheal tube. Other age based formula's for calculating the size of Endotracheal tube include KHINE in children less than 2 years old. KHINE FORMULA = Age/4+3, MOTOYAMA formula in children more than or equal to 2 years old. MOTOYAMA FORMULA : ID in mm = 0.25*(age in years) + 3.5,COLE FORMULA=Tube size=0.25*age+4[5]

But such formulae have their limitations in children of all ages probably due to variety of other reasons airway development while growing up.

The advent of USG has revolutionised the practice of anaesthesia which includes Regional blocks, Vessel catheterization, and airway assessment and management. Ultrasonography is a reliable technique to assess the tracheal sub-glottic diameter which will aid in assessing and selecting an appropriate size ETT especially in children. There are few studies in pediatric population for estimation of size of ETT and its correlation with conventional estimation techniques. Hence the present study aims at comparing two techniques namely aged based formula and ultrasound guided technique to predict appropriate size ETT in children.

AIMS & OBJECTIVES

The objectives of the study were:

1. To compare prediction of appropriate size Endotracheal tube.
2. The number of endo tracheal tube changes between age based formula and ultrasound based technique in children undergoing general anaesthesia

REVIEW OF LITERATURE

Endotracheal anaesthesia in children and infants was rarely performed due to the fear of the procedure being too traumatic and dangerous potentially damaging the airway. It was also noticed that sub glottic stenosis, post-extubation tracheitis,trauma to the mucosa and laryngeal spasm was prevalent. Tracheostomy was prefered in case of long term airway control.

In 1957 cole proposed a formula (Tube size=0.25*age+4) to predict correct size of ET for pediatric patients,other age based formulas like penlingtons were also proposed. But due to wide variation and inaccuracy of the calculated ET size,other complex formulas using multiple variables like age, weight, height, little finger index were used but are not popular in clinical practice[6]

In 1960, there was a major advance due to the development of polyvinyl chloride tubes over the available stiff rubber tubes. Deming in phidelphia and Rees in 1980 pioneered the use of endotracheal intubation on their own pediatric patients and the acceptance of endotracheal intubation was increased however post extubation complications are still present even till date but there is dramatic decrease compared to the past.

In 2012 **christoph Schramm** et.al conducted a study in 50 pediatric patients of <5 years of age to measure the correct size of ETT using ultrasonography before the intubation by measuring the minimal transverse diameter of the subglottic airway in the transverse plane and compared to two age related formulas. They choose uncuffed ETT and observed that ultrasonography facilitates accurate selection of appropriate ETT [7] in pediatric patient's and also reduced the number of reintubations.

In 2012 **Kumkum gupta** et.al studied 112 patients between the age of 3-18 years and measured the subglottic diameter using ultrasound for estimating the correct ETT size and correlated them with the physical indices (Age+height based formula)[8]. They measured in B mode, the transverse air column and the ETT was selected accordingly, optimal size was noted if the leak was between 10-20cms of H_2O.The study showed that direct measurement of subglottic diameter by ultrasonography has significant advantages in predicting the optimal ETT size. This study showed the higher correlation between clinically used and predetermined endotracheal tubes by ultrasonography than predicted endotracheal tube by age and height based formulas.

In 2017 **Demet altun** et.al conducted a prospective study in 152 children of age between 1-10 years who had an adenotonsillectomy under general anaesthesia. The objective of this clinical study was to determine the success of ultrasound in paediatric patients in determining the appropriate size of cuffed ETT and to compare the results with estimate conventional height-based (Broselow) tape[9] and age-based formula (Motoyama and Khine) tube size. They have stated that the subglottic diameter measured by the ultrasound can be a reliable and better predictor for the evaluation of the proper size of endotracheal tube in paediatrics.

In 2018 **Gulnur gollu** et.al conducted study in 61 pediatric patients aged between 2-17 years compared the subglottic diameter in the transverse plane by ultrasound technique and cole and khine age based formula [2,3,5] for estimating the appropriate size of the ETT. Cuffed ETT were employed, and the tube's location was confirmed by ultrasound both before and after the surgery, as well as by an $ETCO_2$ trace. The results of study concluded that the ultrasound method of measuring the ETT size was more accurate than age-based formulae

In 2018 **Rahul pillai** et.al studied in with 49 pediatric population with congenital heart disease the usefulness of ultrasound measurement of minimal transverse diameter of subglottic airway for proper ETT size and compared it with age-based formula and stated that pediatric patients required a larger ETT cuffed tube size [10]compared with age based formula and using ultrasound the measurements as guide for ETT selection was safe and accurate.

In 2019 **Rekha makki reddy** et.al conducted study in 41 children belonging to ASA I,II between the age of 2-6 years by comparing the conventional age based formula with ultrasonographic measurement the subglottic diameter (tracheal column) at the level of cricoid to identify the correct size of ETT. The ETT size was considered appropriate and clinically fit if there was an audible leak when the airway pressure was increased to 15 cm of H_2O. If the leak occurred at less than 15 cm of H_2O, the tube was considered small and trachea was reintubated[9] with an ETT of size greater by 0.5 mm. If there was no audible leak till 25 cm of H_2O, the tube inserted was considered large and trachea was reintubated with ETT of size smaller by 0.5 mm. They observed that US-SD correlates with actual ETT size and is useful in choosing the correct size ETT.

In 2019 **Jianhong Hao** et.al conducted a study in 50 paediatric patients who are undergoing scoliosis surgery they used ultrasound to predict the size of ETT and found that ultrasound is a reliable tool to predict ETT size for patients undergoing thoracic and lumbar scoliosis but patients with cervical scoliosis required a smaller ETT than predicted size.

In 2019 **Essam mahram** et.al conducted a study of forty children of age group between 2-10 years belonging to ASA I and II and compared between age based formula and ultrasound to measure the MTSD to select the endotracheal concluded that age based formula had a strong correlation with the ETT size measured by ultrasound.

In 2019 **Subhi singh** et.al studied in 100 pediatric patients of age 1-5 years and of either gender, they assessed the transverse diameter at the level of cricoid cartilage not at the lower edge or at the midpoint ultrasound (best-fit) [12]and compared to parameters like age , height , weight based formula[3,4,5] and diameter of right and left little finger they came to conclusion that ultrasonography for measuring the subglottic diameter can be a valid approach to determining the right size endotracheal if the air leak was adequate at 15-20cms of H_2O.

Jagadish G sutagatti et.al conducted study in 75 children aged 1-14 years of ASA I, II to determine the accuracy of ultrasonography for predicting correct ETT size and differentiate it with age based formula and height based[3] formula both cuffed and uncuffed tubes were used they have stated that ultrasound is useful for selection of correct ETT size and ultrasound is effective tool for both cuffed and uncuffed ETT.

Gunjan et.al reported in 100 patients of age group of 1-5 years the accuracy of ultrasonography to assess the proper ETT size, and compared it with physical indices based formulae like age based formula, modified cole's formula[5] was used for uncuffed tubes and khine formula[3] for uncuffed tubes was used. height based formula were height was measured using standard tape, transverse air column was measured at the subglottic level using ultrasonography to estimate the correct ETT size. Any resistance faced during intubation or no audible leak when inflated with a pressure of 20cms of H_2O, then the ETT was exchanged with 0.5mm smaller tube.

The study concludes that ultrasonography is an effective tool in predicting paediatric ETT size.

In 2020 a meta analysis by **bhavana** et.al conducted study in 48 studies which were conducted from 2010 to 2020 with total number of 1978 between the age group of neonates till 17 years of age under GA and they have concluded that Compared to standard age-based or height-based formulae in the paediatric age group, [3,4,5,12] use of USG for upper airways is a crucial modality and may reliably predict endotracheal tube size estimations. The US is a highly helpful modality that is currently underused but has the potential to quickly become a crucial tool for airway control. It can assist in accurately determining the needed ETT size, insertion depth, reduce intubation attempts, and confirm proper placement.

BASIC SCIENCES

AIRWAY ANATOMY

Pediatric intubation is one of the most challenging procedure even for an experienced anesthesiologist due to the difference in the anatomy of airway in pediatric age group and adults.[13,14] In children, the embryological growth and development as well as the transformations during the course of growth and development necessitates the requirement for a different technique, approach and the devices used in them.

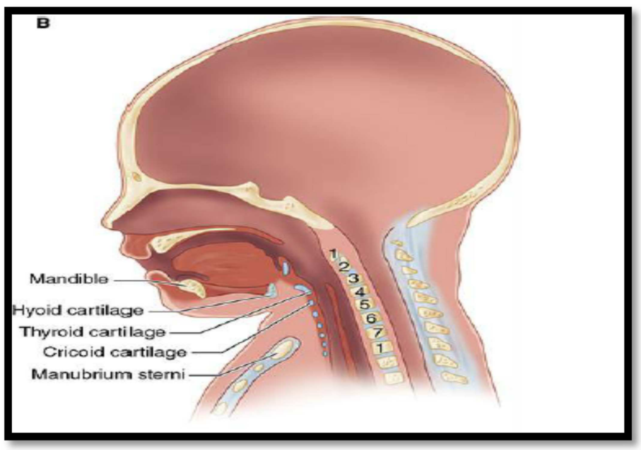


Figure 1: Pediatric Airway Anatomy

ANATOMY

The development of the skull is from a cartilaginous and membranous neurocranium. It gives rise to the following parts:

Membranous neurocranium- the cranial vault, Cartilaginous neurocranium- skull base. The skull base modelling is a dynamic process which involves communal influences among the cranial base, face, pharynx and the palate. There is a predominance of the neural influences owing to the prompt growth of the brain where as there is a major role of nasal influences in neonates and young children. In relation to the body size, children have a correspondingly bigger head and occiput. Thus there is a higher probability of airway obstruction due to more flexion of the neck when the child is supine[15].

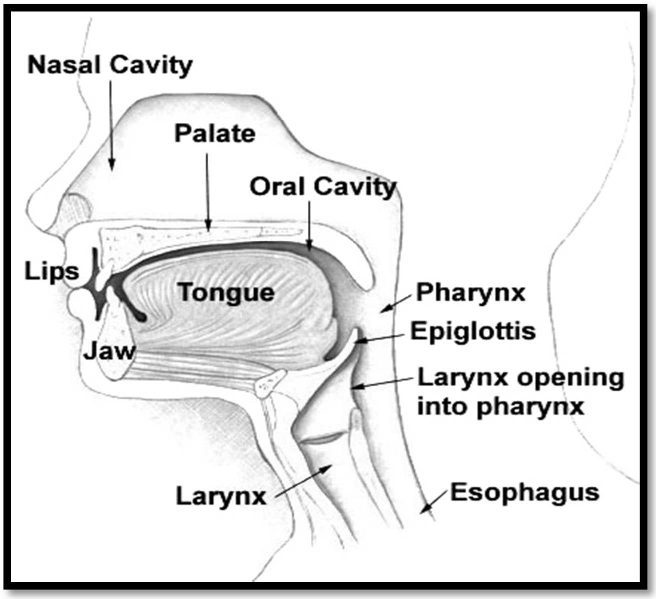


Figure 2: Airway anatomy

NOSE

The nose, composed of nasal cavity and external component of the nose has its origin from the cranial ectoderm[16]. The formation of the external component is by the nasal part of frontal bone, the frontal process of maxilla and the nasal bones. The nasal septum divides subdivides the nasal cavity into 2 compartments. This opens exteriorly via the nares and posteriorly via the choanae into the nasopharynx. Sensory innervation of nasal mucosa- maxillary division of trigeminal nerve. During developmental stages, the palatal processes are fused and directed posteriorly. Under this influence the nasal cavities extend. Palatal processes are separated from oral cavity by a membrane, this membrane becomes thinner progressively and rupture, which leads to choanal atresia. Children have relatively more mucosa and lymphoid tissue compared to adults, thus making a child's nose soft and distensible. Irregular development of nasomaxillary complex or nasal injury can cause deviated nasal septum which can occur in any age during childhood [17]. Each side of nasal cavity has the following parts - roof, floor, medial wall and lateral wall. Roof is directed upwards and backwards, thus forming the bridge of the nose. Floor is concave in shape from side to side.The nasal septum forms the medial wall. The lateral wall is formed by a bony framework comprising 3 turbinate bones- superior, middle and inferior turbinates. Below the inferior turbinate lies the major nasal air passages. Hence, during nasal intubation, the endotracheal tube should be directed backwards along the floor in such a way that it passes through the major nasal air passages. Nasal intubation can become difficult when there is resistance while passing the tube. One of the reasons for resistance is hypertrophied inferior turbinate at the posterior end [18].Nasal breathing also hampers the airflow by increasing the resistance [19]. Nasal apertures being small in children, can be blocked easily by edema, secretions and blood. Such conditions may worsen the condition in case of infants by increasing the work of breathing, as infants are obligate nasal breathers. It also adds up to difficulties in airway management under general anaesthesia in infants.

PHARYNX

The pharynx is the common pathway of upper respiratory and upper GI tracts. It communicates with nasal cavity to form nasopharynx, with oral cavity to form oropharynx and with larynx to form laryngopharynx.

NASOPHARYNX

It lies above and posterior to the soft palate and nasal cavity respectively. It continues as the oropharynx via pharyngeal isthmus. During act of swallowing, the pharyngeal isthmus is sealed off thus facilitating deglutition. Its sensory nerve supply is by trigeminal nerve and glossopharyngeal nerve [20]. During development, remodeling of palate occurs along with changes in angulation of the skull base. This increases the depth of nasopharynx thus forming an enlarged nasal airway in adult. The lateral wall has the opening of the pharyngeal part of the Eustachian [pharyngotympanic] tube. Nasopharyngeal tonsils are present on the posterior wall and roof of the nasopharynx. Breathing maybe obstructed due to enlargement of the adenoids and during instrumentation of the nose they may also get dislodged.

OROPHARYNX

It extends between the soft palate and the tip of epiglottis. Anteriorly it is attached via the gloss epiglottic folds to the base of tongue. The valleculae lies between these folds. Sensory innervation- Superior laryngeal branch of the vagus nerve and the glossopharyngeal nerve [afferent impulses from base of tongue and valleculae. Stimulation of pharyngeal wall during laryngoscopy and tracheal intubation results in reflex circulatory-responses. The Waldeyer's ring is a collection or lymphoid tissue located at the entrance of the oropharynx [consisting of bilateral palatine tonsils, lingual tonsils, nasopharyngeal and tubal tonsils]. Breathing may be obstructed due to inflammation of lymphoid tissues which can make laryngoscopy challenging due to masseter spasm or increase in size of the tissue. Tonsillar hypertrophy and asymmetry can also occur [21]. The presence of a relatively larger tongue in children further reduces the oral cavity size and may obstruct the airway.

They also have a decreased muscle tone which may contribute to the same. In supine infants, the tongue has a tendency to flatten against the soft palate during inspiration and it might persist in the same position during expiration. Anterior displacement of the cervical spine and extension of head at atlanto-occipital joint results in an improvement in the hypo-pharyngeal airway patency but may not change the position of the tongue.

LARYNGOPHARYNX

It extends from epiglottis to the inferior extent of the cricoid cartilage. At the center, the larynx bulges posteriorly thus creating a recess on each side which is known as piriform fossa. Swallowed and sharp foreign bodies are commonly impacted at this site.

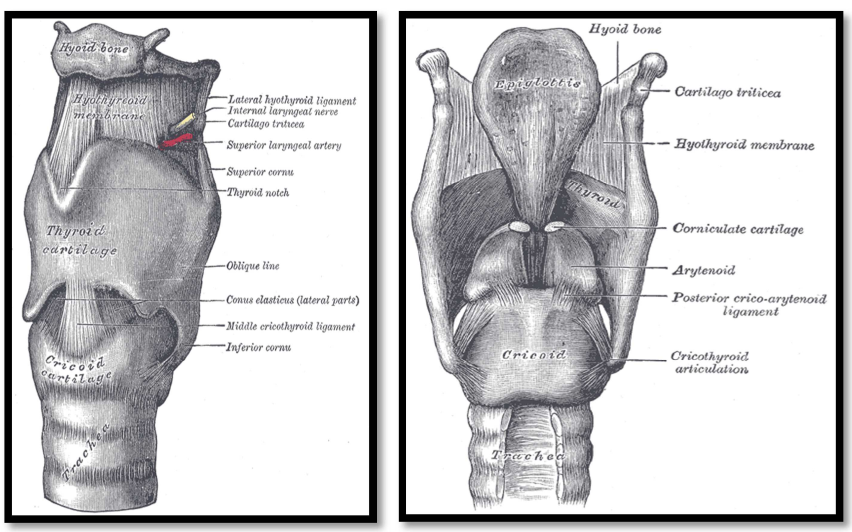


Figure 3: Anatomy of larynx

LARYNX

The larynx is located between the pharynx and the trachea. It extends from the base of the tongue to the cricoid cartilage. Function- phonation and protection of the tracheo-bronchial tree during the act of swallowing and coughing. Development- begins around 3rd gestational week. Laryngotracheal tube is formed from the ventral-wall of the foregut. At around 41 days of gestation, a definite larynx can mostly be identified. By approximately 7 weeks of gestation Chondrification of the cricoid and thyroid cartilage begins and by 10 weeks a primitive glottis is formed and true vocal cords split. A failure in this process may result in formation of a congenital laryngeal-web or atresia of larynx may occur. A trachea-oesophageal fistula may result if there is an incomplete division of embryonic foregut [anteriorly- trachea and posteriorly-oesophagus]. The larynx has 9 cartilages- thyroid, cricoid, aryteoids[paired], epiglottis, corniculate[paired] and cuneiform[paired]. These cartilages form an articulating framework and are linked by ligaments that move in relation to one another by laryngeal muscle action [18].The thyroid cartilage is the largest and is deficient posteriorly and anteriorly it forms the laryngeal prominence. The cricoid cartilage lies beneath the thyroid cartilage and is signet ring shaped with the broadest part posteriorly. It is the single complete ring shaped cartilage. The lower border lies at the level of the 4th cervical vertebra at birth and at the level of the 5th cervical vertebra by 6 years of age. In adults it lies at C6 level. The airway in children may get severely compromised due to mucosal edema at this site accounting to its small size and complete ring structure. Subglottic stenosis may be seen in younger children due to prolonged and repeated tracheal intubations. The arytenoids articulate behind the cricoid cartilage at its postero-superior aspect. The vocal process [anterior process] is present on each arytenoid and the vocal ligament is attached to it. The triangular corniculate cartilage lies at the apex of each of the arytenoid cartilage and is attached via a perichondrium. The vocal folds that are covered with mucosa form the true vocal cords whereas the false vocal cords [vestibular folds] are formed by mucosa which covers the thyro-arytenoid muscles [18]. Laryngospasm occurs as a result of reflex adduction of the false and true cords and it may be due to surgical stimulation, inadequate depth of anaesthesia or local stimulation of the larynx. The joint formed between the cricoid and thyroid cartilage is covered by an elastic and tough connective tissue called the cricothyroid membrane. A surgical airway is secured by creating an incision or puncture through this membrane. A leaf shaped structure present at the posterior aspect of the thyroid cartilage and attached to it by the thyroepiglottic ligament is the epiglottis. The epiglottis is infants is softer and narrower, it is also deeper and omega shaped in neonates and may have a V-shaped appearance in some babies. It is situated more horizontal when compared to adults in whom the epiglottis is broad with the axis parallel to that of trachea. The epiglottis can be lifted by using a straight blade [millers blade] which maybe useful for tracheal intubation in smaller children.In the aryepiglottic folds, Cuneiform cartilages lie anteriorly to the corniculate cartilages.A more acute angle is formed between the laryngeal inlet and the base of tongue due to a more superiorly located larynx which may make visualization of the laryngeal structures more difficult. A shoulder/neck roll placed during laryngoscopy may aid to reduce the hyper-flexion of the neck of an infant which is due to a relatively larger occiput in them.Blood supply- The superior laryngeal artery [branch of superior thyroid artery]. It is also supplied by the inferior laryngeal artery [branch of the inferior thyroid artery].Nerve supply- vagus nerve by its recurrent and superior laryngeal branches.The internal laryngeal branch is formed from the superior laryngeal nerve and it runs below the piriform fossa mucosa. The vagus nerves innervate the inferior surface of the epiglottis and laryngeal inlet. Hypotension and bradycardia may occur during laryngoscopy as a consequence of vagal reflex. This is usually seen with the use of a straight blade. The glossopharyngeal nerve innervates the superior surface of the epiglottis and vallecula [22]. Recurrent laryngeal nerve damage will result in vocal cord paralysis of the corresponding side, thus making it lie in the midline motionless and at a lower level compared to the opposite side. A complete loss in vocal power is seen in cases with bilateral paralysis and a valve like obstruction may be noticed during inspiration thus causing inspiratory stridor and dyspnea.When compared to an adult airway, paediatric airway is more compliant with a less well developed cartilaginous support thus increasing the susceptibility to a dynamic collapse of the airway when there is airway obstruction. A loss of the laryngeal muscle tone accounts for airway obstruction during general anaesthesia. Loss of pharyngeal muscle tone leads to obstruction of the airway at the epiglottis and soft palate level. The pliability and less rigidity of the paediatric laryngeal structures makes it more prone to a congenital abnormality, laryngomalacia. The most important challenges faced during positioning and induction of a paediatric patient is due to the larger size of their head compared to the body. Also a short neck with a large occiput makes it difficult to perform laryngoscopy in these patients.They are more prone to difficulty in mask ventilation and intubation due to the presence of a larger tongue, shorter mandible, prominent tonsils and adenoids that accounts for a reduced upper airway space. Until the age of 5 months children are also considered obligate nose breathers.

The decreased strength in the diaphragmatic and intercostal muscles is due to the paucity in the type I muscle fibres. There can be a dynamic obstruction when negative pressure ventilation is done due to the presence of more horizontal ribs, flexible cartilaginous rings of the trachea and a more protrubent abdomen. The use of anaesthetic drugs can further reduce the upper airway muscle tone. The smaller airways are scarce in the lungs and also the maturation of the alveoli is not complete. The hypopharynx is usually narrow and shorter in length. The narrowest part of the upper airway is at the cricoid cartilage and the larynx is situated more anteriorly at the level of the C4 vertebra. The epiglottis is situated across the glottis opening is more floppy and U shaped. Endotracheal intubation maybe traumatic at times due the right angle formed between the vocal cords and trachea which increases the probability of the collision with the anterior commissure of the vocal cord. The challenges faced due to positioning can be avoided by placing a folded towel under the shoulder of the patient. This often reduces the flexion of the neck and thus can make laryngoscopy easier. The extension should not be more as it may make the larynx more anterior and thus make visualization more difficult.

HEAD	• Large occiput
MOUTH	• Relatively large volume of tongue reduces available space for instrumentation • Edentulous
NECK	• Cephalad placement of larynx (C3-C4) • Omega shaped epiglottis • Caudally slanted vocal cord which are placed at arytenoids • Narrowest cricoid ring • Short trachea
TRACHEOBRONCHIAL TREE	• Right main bronchus is acutely angled at carina • Turbulent gas flow till fifth bronchial division.

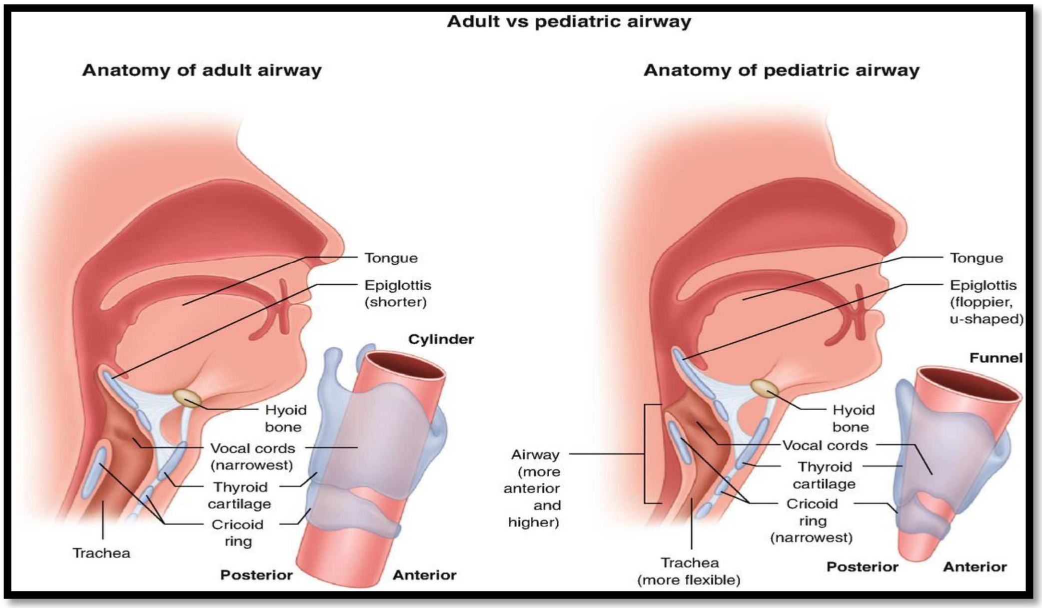


Figure 4: Differences between adult and pediatric airway

ENDOTRACHEAL TUBE[23]

Endotracheal tube is made of polyvinyl chloride (PVC), red rubber and silicon. Polyvinyl chloride (PVC) substance is mostly used in disposable tubes they are inexpensive compatible with tissue non toxic, thermo labile ,less likely to kink , less risk of transmission of infection. Red rubber tubes can be cleaned, sterilized and reused multiple times, they are toxic to tissue, less opaque. Silicon tubes are expensive,reuseable, and less thermos labile

PARTS OF ENDOTRACHEAL TUBE

- Machine end
- Murphy eye
- Patient end
- Markings to assess depth of insertion
- Radio opaque to confirm the correct placement of tube visible on X ray.

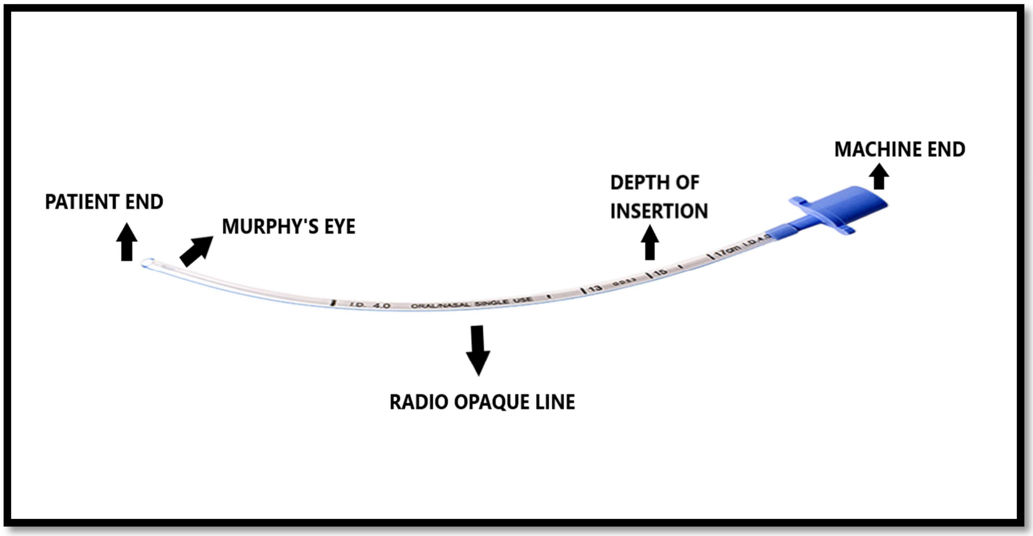


Figure 5 : Uncuffed Endotracheal tube

SELECTION OF ENDOTRACHEAL TUBE[24]

In pediatric population uncuffed ETT are used for intubation. Various conventional methods are available in determining the ETT size PENLINGTON formula: Age < 6 years- age/3 +3.5 = Internal Diameter (ID) of Endotracheal tube. Age > 6 years – age/4 +4.5= Internal Diameter (ID) of the Endotracheal tube. Other age based formula's for calculating the size of Endotracheal tube include KHINE in children less than 2 years old, MOTOYAMA formula in children more than or equal to 2 years old. Several other conventional methods are also present like height based formula, weight based formula, width of little finger.

ULTRASONOGRAPHY[25,26,27,28]

Ultrasounds are acoustic waves characterized by a frequency above the threshold of human detection (above 20 000 Hz). In the field of medical imaging, frequencies ranging from 2 to 15 MHz are routinely used. US probes contain piezoelectric materials whose mechanical and electrical properties result in the production and transmission of sound waves, and their reception in the form of echoes from tissues.

According to the pattern of reflection of the received sound waves, which depends upon the different impedance of each tissue to ultrasound, the transducers recreate the shape and the internal structure of the explored organs In the presence of different acoustic interfaces, the majority of echoes are derived from tissues shown as white and called hyperechoic. In the presence of few acoustic interfaces, echoes are formed much less; the structures appear black and are called hypoechoic. An inverse relationship exists between the US frequency and its ability to penetrate into tissues (e.g., low frequency and high penetration into tissues), and there is a direct relationship between frequency and potential image resolution.

When examining airways, superficial structures (2–3 cm below the skin) are visualized with 7.5 MHz linear probes, and deep structures with 5 MHz curved-array probes. Airways are mostly superficial structures, but their content of air prevents their deeper parts from being properly visualized. Similarly, the presence of air inside the filled cuff of an endotracheal tube makes its visualization impossible. Air is a weak conductor of US; at the tissue–air interface ultrasounds are reflected and artifacts created. For this reason, transducers with variable frequencies should be used, along with cross-beam imaging, in order to obtain images of good quality, or it may be necessary to adopt tricks to optimize the US reflection pattern, e.g., filling the cuff of an endotracheal tube with fluids (e.g., saline) or air bubbles, or visualizing the tube during its passage through the larynx.

Ultrasound waves in the frequency range of around 2 to 15 megahertz have a wide range of diagnostic and treatment purpose in the field of medicine. The ultrasonography works on the principle of Piezoelectric effect. This effect converts mechanical / kinetic energy into electrical energy by deformation of crystals.Piezoelectric effect can also be reversed i.e., by electrical energy the crystals can be oscillated to form ultrasound waves (mechanical energy).

The ultrasound transducer has the function of producing the ultrasound by the above said mechanism. This ultrasound produced travels through tissues and gets reflected back. The returned echo waves after reaching the transducer gets changed to electrical energy which is later processed and produce an image. The transducers work in a range of frequencies. Transducers with higher frequencies (5 – 7.5 MHz) are used in imaging superficial structures whereas the ones with lower frequencies (2.5 – 3.5MHz) produce images of deeper structures

It is on the surface that lies between tissues of varying density, the ultrasound gets reflected. If the difference in densities is higher, the sound waves that get reflected is also high and the opposite also holds true. Therefore, with very high difference of densities (bones, air, calculi) the sound will be completely reflected back. This produces the acoustic shadowing. If the tissues are homogenous in their densities, then echo-free images are seen (blood, urine, ascites).

Transducer -This is the hand-held part of the ultrasound machine. It has the function of interconverting the energies (electrical and mechanical) based on piezoelectric effect. They contain lead zirconate titanate crystals commonly.

It comprises 5 major components:

- Crystals: possessing piezoelectric property. Can be arranged in either linear or curvilinear manner.
- Electrodes: positive and ground. For electrical connection
- Damping block: to dampen stray sound waves
- Matching layer: For proper transmission of sound waves to one or multiple tissues.
- Housing.

They produce the ultrasound waves in either linear (sequential) arrays or phased array.

Linear Transducer:

- The piezoelectric crystals – Linearly arranged
- Produce rectangular ultrasound beam
- Produce rectangular ultrasound beam
- Used for superficial imaging.
- Footprint – wide with frequency of 2.5 – 12MHz at the centre in 2D imaging probe
- and frequency 7.5 – 12 MHz at the centre in 3D imaging probe.
- Applications of linear probe in anaesthesia:
- Airway assessment

- Visualisation of superficial structures like Brachial plexus
- Vascular access
- Vascular examination

Curvilinear Transducer:

- The Piezoelectric crystals – curvilinear arrangement.
- They produce convex ultrasound beam.
- Used to image deeper tissues.
- As depth of imaging increases, image resolution decreases.
- Foot print is wide with central frequency being, 2.5 – 7.5MHz for 2D imaging and 3.5 – 6.5MHz for 3D imaging.
- Applications of curvilinear probe in anaesthesia:
- Deep nerve blocks

ULTRASONOGRAPHY AND AIRWAY[29]

Normal appearances of standard anatomical structures

It is important to be consistent with the imaging parameters and settings in order to be able to develop a mental database of normal appearances. Below are the expected echogenic appearances of different anatomical structures when scanned at higher frequencies.

Fat

As a general rule of thumb fat appears hyperechoic (bright)—such appearances can be consistently seen in the subcutaneous fat, but also in between structures in the neck.

Muscle

Muscular structures are generally of lower echogenicity (hypo echoic/dark) on ultrasound. Within these one can see hyperechoic linearity from the connective tissue supporting the muscular fibers. On transverse imaging these can be seen as brighter dots, whereas they appear more linear when the muscle group is imaged in the longitudinal plane. Hyper echogenicity may be appreciated around the muscles from the supporting fascial structures.

Bone

Ultrasound travels poorly through bone due to the density of the latter—When bony structures are encountered, this results in a very bright line/interface at the surface of the bone and significant posterior acoustic shadowing behind this limiting, or even eliminating the information which can be obtained deep to the bony structures. In such a case, looking through an alternative window should be attempted if possible

Cartilage

Appearances of cartilaginous structures can be variable depending on the density and how much calcification is present within. However, as a general rule, cartilage appears hypo echoic (low echogenicity/dark) when compared to the fat around it.

Air

Air bubbles result in tiny hyper echoic (bright) foci— these often have ‘ring down artifact’ an appearance quite characteristic resulting in a ‘comet-tail appearance’ secondary to resonance phenomenon by the air bubbles. When a whole interface of air is encountered (for example at the lung surface) this appears hyper echoic with similar artifacts seen deep to the superficial surface.

Fluid

The echogenic appearances of fluid is variable and depends on the consistency and density of the material in question. Clear fluid (such as urine in the bladder) appears anechoic (black). Similar appearances are seen in cysts containing clear fluid that can be encountered in the neck (ex: cystic hygroma or in a simple thyroid cyst, blood in vessels appear dark).

Vascular structures

These appear as hypo echoic round or oval structures in the transverse plane and linear tube-like structures in the longitudinal plane. Flow is identified if interrogated with Doppler ultrasound. Venous structures compress with moderate pressure unlike arterial counterparts where significantly higher pressure is needed in order to compress the vessels.

Essential scanning protocols

A main advantage of ultrasound is the dynamic nature of the real time picture allowing visualization of the changes of anatomy and locations in real time. However, at the same time, this is also a potential weakness of this modality as a separate operator is required independently to instrument the airway.

The following section describes scanning protocols that are suitable to identify the normal ‘static’ and ‘dynamic’ airway anatomy of children.

Mouth/oropharynx and tonsils

Identification and localization of oral structures:

Through such an ultrasound window, depending on the size of the patient, it is often possible to visualize all the anatomical structures from the mentum proximally to the hyoid bone distally. This may necessitate changing to a curvilinear probe in a larger child. Identification and localization of the tonsils: Foci of echogenicity in the tonsils correlate with air within the crevices of this structure. Scanning the contralateral side of the face/upper neck will demonstrate mirror images.

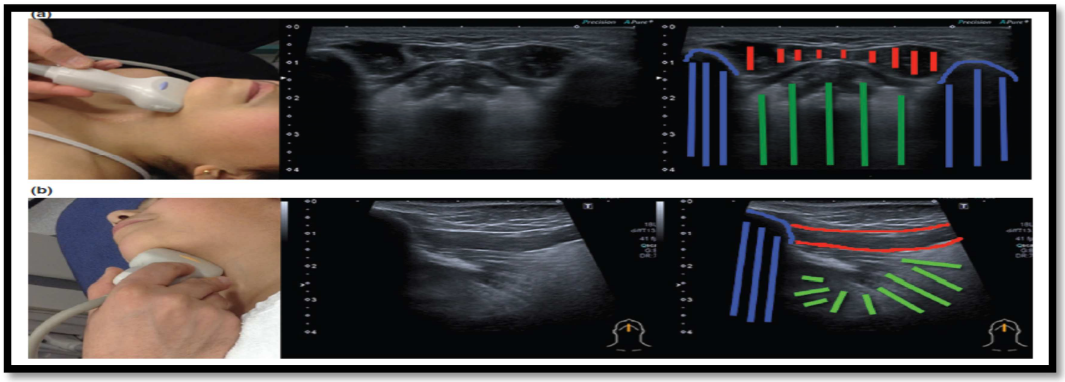


Figure 6: USG image of Mouth/oropharynx

Infrahyoid region

The hyoid bone is normally still cartilaginous in young children and appears hypoechoic. As it calcifies it increases in echogenicity and casts a posterior acoustic shadow. Below the hyoid, suitable images can be obtained again in transverse and longitudinal plains. This area allows good access to the larynx with full access and visualization of its internal structures. With the patient in a straight supine position, a transverse image allows identification of the upper larynx, false vocal cords superiorly, true vocal cords inferiorly, and continuation of this into the upper trachea and esophagus at the level of the thyroid gland.

The false cords demonstrate more echogenicity lateral to them due to the presence of fat. Inferior to the level of the false cords are the true cords, and the larynx continues as the cricoid cartilage. Between the cricoid cartilage and the thyroid cartilage, the thin cricothyroid membrane can be identified. Beyond the cricoid cartilage, the trachea starts.

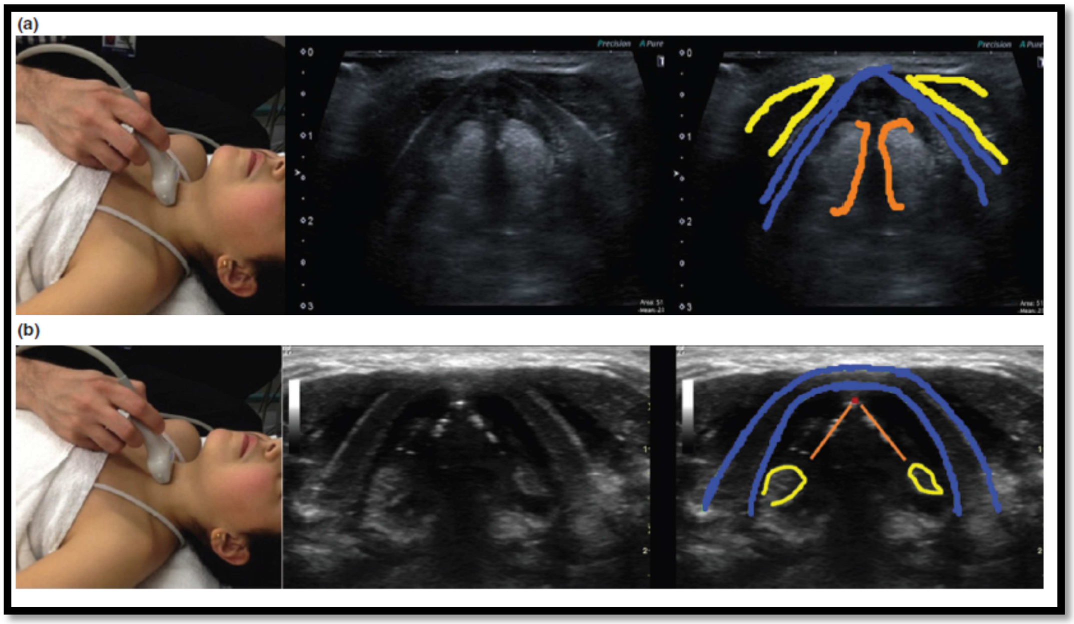


Figure 7: USG of infra hyoid region

The trachea

With the child in a supine position and the head facing perfectly forward, the trachea can be well visualized just inferior to the larynx above the suprasternal notch.

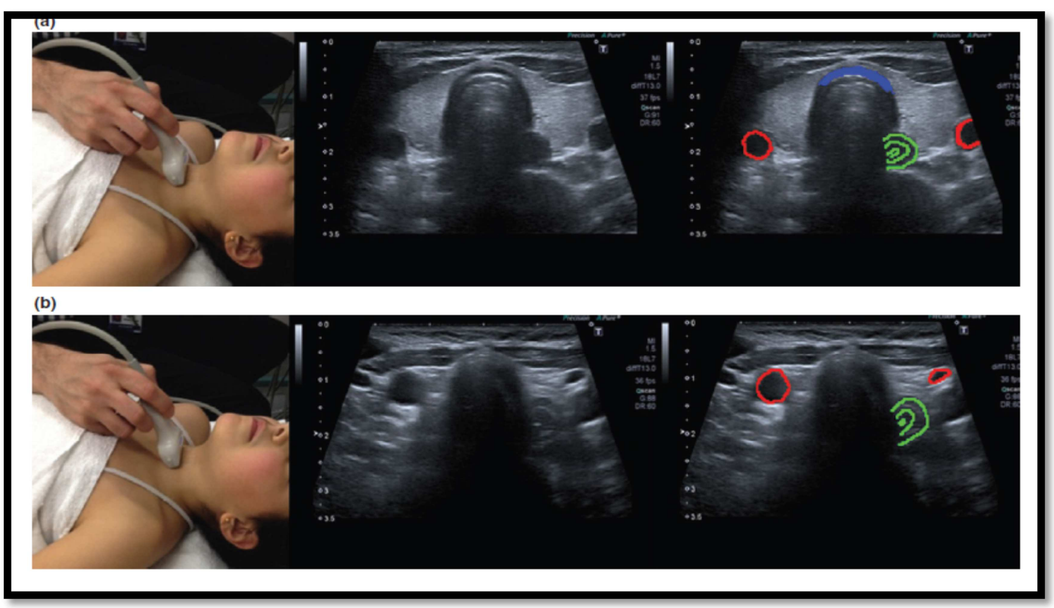


Figure 8: USG of trachea

MATERIALS AND METHODS

Source of data: The present study titled "COMPARISION BETWEEN ULTRASOUND BASED TECHNIQUE AND AGE BASED FORMULA IN PREDICTION OF APPROPRIATE ENDOTRACHEAL TUBE SIZE IN CHILDREN "ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY" was conducted in paediatric patients between age group of 1-8 years undergoing elective surgeries under endotracheal General Anesthesia between 1st January 2021- 31st December 2021 at "KLE'S Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belagavi".

Study design:12 Months hospital based randomised study

Sample size: Total sample size: 50

Sample size calculation: The minimum sample size formula based on mean and standard deviation where n = $z\alpha$ is linked with the level of significance and $z\beta$ is linked with the power of the test. For 5% level of the significance $z\alpha$ =1.96 and $z\beta$ =0.84 for 80% power of the test. The mean of the first group (4.43) and is the mean of the second group (4.59). s1 is the standard deviation of the first group (0.23) and s2 is the standard deviation of the second group (0.09).With these values the sample size obtained was 19 in each group. To make the study more confirmative, the sample size was raised to 25 in each group.

The criteria for the study was following:

Inclusion Criteria:

- Consent provided by parents and guardians.
- Children aged between 1-8 years of age.
- ASA physical status I and II.
- Patients undergoing elective surgeries under general anaesthesia.

Exclusion Criteria:

- Patients whose parents are not consenting for the study.
- Patient having upper respiratory tract infection, tracheal and laryngeal pathology.
- Patients undergoing emergency surgeries.
- Patients with airway difficulties.
- Previous history of child requiring an exceptionally large or small size tube.

After Institutional review board and Ethical committee clearance, parental consent and having met inclusion and exclusion criteria patients were randomized based on computer generated randomization table into one of the two groups of 25 each.

Group A

Tracheal intubation performed with an Endotracheal tube of the size as determined by the age based formula.

Group B

Tracheal intubation performed with an Endotracheal tube of the size as determined by ultrasonographic assessment of subglottic diameter.

All children were kept NBM for at least 6 hours prior to surgery. On the day of surgery, after confirming the NBM status and consent was ascertained in the recovery room all patients were premedicated with Inj.Glycopyrrolate (0.005mg/kg) and Inj. Ketamine(5mg/kg) IM and then shifted to operation theatre. Inside the operation theatre standard monitoring devices like ECG, pulse oximeter and NIBP were connected. Intravenous access was secured using 22G or 24G IV cannula and ringer lactate IV infusion was started.

Group-A: ETT tube size was estimated by using age based formula

- In children < 6years - Age/3+3.5
- In children > 6years – Age/4+4.5

Group-B: ETT tube size was estimated by measuring the subglottic diameter using high resolution B ultrasonography

Patients were placed in supine position with head at neutral position and the probe of ultrasonography was placed in midline. True vocal cords were localized seen as a pair of hyperechoic linear structure moving along with respiration and swallowing. Then the probe was moved caudally to visualize the cricoid arch to avoid confusion between the cricoid cartilage and tracheal ring. The measurement of tracheal diameter was taken as a transverse air column diameter done at cephalic half of the cricoid cartilage which is narrower than the caudal part of cricoid cartilage.

This was considered to be same as the outer diameter of ETT. The appropriate size of internal diameter of ETT corresponding to outer diameter were then selected.

All patients were pre-oxygenated with 100% oxygen for 3 minutes and then premedicated with Inj.Midazolam (0.05mg/kg) and Fentanyl (2mcg/kg) anaesthesia was induced with Inj.ketamine (1-2mg/kg) and Inj. Succinyl choline (2mg/kg) was administered to achieve skeletal muscle paralysis to facilitate endotracheal intubation. Uncuffed endotracheal tubes were used. Endotracheal tube intubation was done. The following parameters were used to assess whether the selected ETT is of an appropriate size:

- ETT passing smoothly through the glottis
- No audible leak at 10-20cms of H2O
- A square wave capnography on ventilation.

After insertion of the ETT the appropriate size was checked by conducting a leak test if the leak was10-20cms of H_2O then it was considered appropriate if a leak of<10cms of H_2O, and excessive leak >20 cms of H_2O was inappropriate and the tube size was changed. The number of ETT changes in each group were also noted.

STATISTICAL ANALYSIS: The study was focused on comparison of two groups. For the continuous quantitative variables mean and standard deviation was calculated. The inter group continuous variables were compared using suitable tools of statistics like unpaired student’s t test. Two quantitative variables, within a group, were compared using student’s paired t test.

The categorical data are expressed in terms of rates, ratios and percentages. The association between the outcome, clinical and demographic characteristics was tested using Chi-square test or Fisher's exact test.

Discrete variables were represented by median. Nonparametric tests were used for comparing discrete variables. Suitable graphs were used to depict the comparison.

RESULTS

The study entitled "COMPARISION BETWEEN ULTRASOUND BASED TECHNIQUE AND AGE BASED FORMULA IN PREDICTION OF APPROPRIATE ENDOTRACHEAL TUBE SIZE IN CHILDREN –"ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY"

Total 50 patients were divided into two groups, 25 in each group

GROUP A – Age based formula

GROUP B – Ultrasound based technique

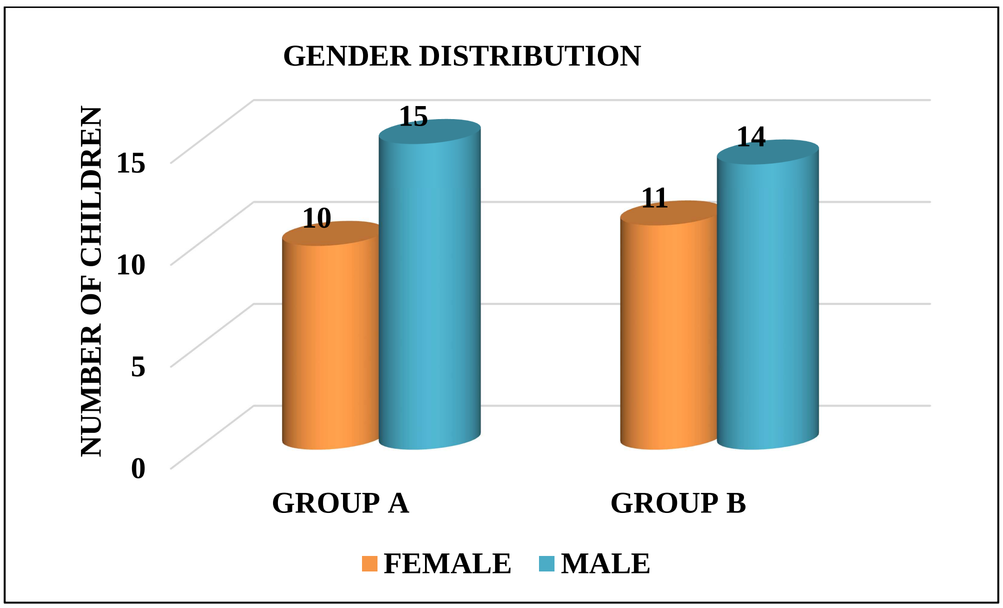
The results were measured and analyzed as follows

GENDER DISTRIBUTION

There were ten (40 %) females and fifteen (60%) males in Group A and eleven (44%) females and fourteen (56%) males in the study. No statistical significance was present.

	GROUP A		GROUP B	
GENDER	**NUMBER**	**%**	**NUMBER**	**%**
FEMALE	10	40	11	44
MALE	15	60	14	56
TOTAL	**25**	**100**	**25**	**100**

Table 1: Gender Distribution



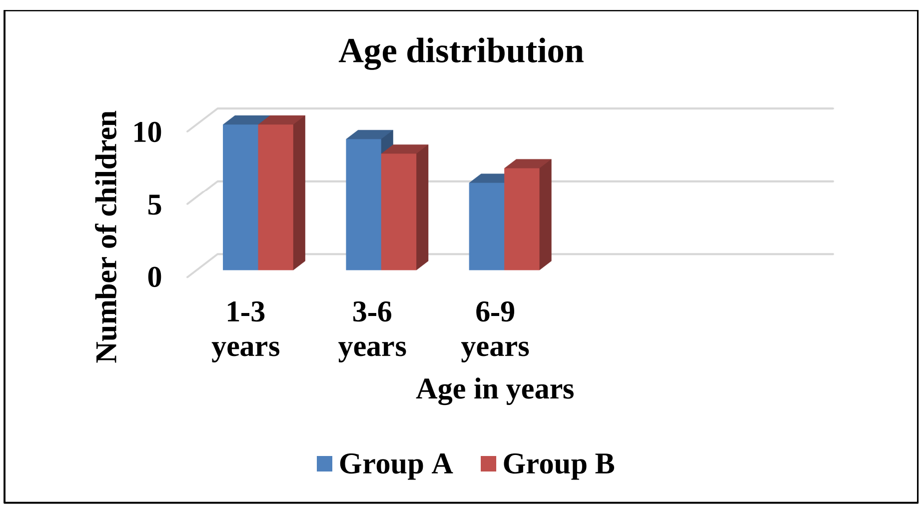
Graph 1: Gender distribution

AGE DISTRIBUTION

The minimum age was 1year, and the maximum age was 8years.The mean age 4.25 was and the standard deviation of 2.56 in group A and mean age 4.60 and standard deviation 2.42 in group B. In the age group from 1-3years there were 10 (40%) children in group A and 10 (40%) children in group B. Age group from 3-6years there were 9 (36%) children in group A and 8 (32%) children in group B. Age group from 6-9years there were 6(24%) children in group A and 7(28%) children in group B. No statistical significance was present.

	GROUP A		GROUP B	
AGE	**NUMBER**	**%**	**NUMBER**	**%**
1 – 3	10	40	10	40
3– 6	9	36	8	32
6 – 9	6	24	7	28
TOTAL	**25**	**100**	**25**	**100**

Table 2: Age distribution



Graph 2: Age distribution

WEIGHT DISTRIBUTION

In the present study the Mean weight was 12.51 and standard deviation was 5.61 in Group A and Mean was 4.60 and standard deviation was 2.42 in group.

APPROPRIATE ESTIMATION OF SIZE ETT BY AGE BASED FORMULA AND ULTRASOUND

	Appropriate	Percentage %	P value
Estimated size by age based formula	**16**	**64**	**0.002**
Estimated size by USG	**24**	**96**	

Table 3. Appropriate estimation of ETT

The percentage of appropriate ETT size estimated in age based formula group was 64% and that of ultrasound group was 96% p value of 0.002 which is statistically significant.

NUMBER OF ETT CHANGED GROUP A AND GROUP B

In present study the number of ETT changed was 20% in group A and zero in group B, p value obtained by using chi square test is 0.0206 which shows that the proportion of ETT changed is significantly more in group A compared to group B.

	GROUP A		**GROUP B**		**P value**
ETT CHANGES	**NUMBER**	**%**	**NUMBER**	**%**	**0.0206**
Not Changed	20	80	25	100	
Changed	5	20	0	0	
TOTAL	**25**	**100**	**25**	**100**	

Table 4 Appropriate ETT placement in both the groups

DISCUSSION

Intubation in pediatric population is quiet challenging task even for an experienced anaesthesiologist. Difficulties have been faced in determining the appropriate tube size using various methods like age based formula, based on weight, little finger diameter. Paediatric airway sonography is constituted by homogenous cartilages without calcification and hyperechoic mucosal air interface. These structures are encircled by isoechoic thyroid and hypoechoic constrictors, the transverse diameter was precisely and accurately measured with USG. While a child was breathing spontaneously or paralyzed the narrowest diameter is the transverse diameter. [3,4,5] Both transverse diameters at the level of vocal cords and cricoid cartilage are lesser when compared to anterior posterior diameter.

A total of 50 paediatric patients aged from 1 to 8 years old who were scheduled for surgery under general anaesthesia were randomly divided into one of the group each with 25 patients. Present study aimed in measuring the appropriate ETT in two groups. In group A the age based formula was applied in children <6 years = Age/3 +3.5 and in children >6years = Age/4+4.5. In group B, ultrasonography was employed. The gender distribution in two groups did not differ significantly from one another. Age group from 1 to 3 years made up majority of the research participation. The demographic profile and patient characteristics between the two groups were not significantly different.

In our study the probe was placed at the level of cricoid cartilage which are hypoechoic structures taken as reference point to measure the subglottic diameter. In study done by shibasaki et.al the probe was placed at the lower edge of the cricoid cartilage E. J. Kim et al in their study adopted transverse measurement at the level of subglottic diameter over antero posterior diameter, which is similar to our study. Because of the subglottis oval shape, the transverse diameter is marginally less than the AP diameter[7,8]; thus, measuring the transverse diameter of the subglottis considered to be the most accurate method for determining the maximum permitted ETT diameter.

In the current study uncuffed endotracheal tubes were preferred in view of preventing trauma while intubation, and also the tubes to have lesser outer diameter than cuffed tubes. similar to the study by Surabhi .et.al even they used uncuffed ETT and has similar point of view regarding uncuffed ETT[5].

In the present study the percentage of assessment of appropriate ETT size in age based formula was 64% and with USG guided technique was 96% with a p value of 0.002 which proves to be statistically significant which correlates with studies done by Bae JY et al. who observed the percent to estimate correct ETT size was 60% by ultrasound and 30% by age based formula. In a similar study done by Schramm et al the percentage to predict appropriate size ETT compared with ultrasound was 48% compared to 24% in the age based formula.

In present study the number of ETT change was 20% in group A and no ETT was changed in group B, p value obtained was 0.0206 which shows that the proportion of ETT changed is significantly more in group A compared to group B which correlates with the study done by Subhi singh et.al were the success results of age based formula was 95% and that of ultrasound based technique was 100%. proving that ultrasound based technique promotes the reduced number reintubations and prevents traumatic intubations

SCOPE AND LIMITATION

- Limiting factors in present study was sample size was small.
- Age group between 9-12 years was not included.
- Larger sample size is required to validate the study results.
- Application of ultrasound technique in older children further studies have to be done.

SUMMARY

The study titled "COMPARISION BETWEEN ULTRASOUND BASED TECHNIQUE AND AGE BASED FORMULA IN PREDICTION OF APPROPRIATE ENDOTRACHEAL TUBE SIZE IN CHILDREN "ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY"

In the present study 50 pediatric patients of either gender between 1-8 years of age belonging to ASA I and II posted for elective surgery. After Institutional review board and Ethical committee clearance, parental consent and having met inclusion and exclusion criteria patients were randomized based on computer generated randomization table into one of the two groups of 25 each. In Group A ETT size was estimated by age based formula and in Group B by using ultrasonography by measuring the subglottic diameter.

The present study shows the percentage of estimation of appropriate ETT size in age based formula was 64% and in USG guided technique was 96% with significant p value 0.002 and the number of ETT changes was 20% in age based formula and no change in USG based technique with p value 0.0206 which is statically significant.

In conclusion, the present study it is found that the estimation of appropriate size of ETT done ultrasonography is better in predicting the size of ETT than age based formula.

CONCLUSION

In conclusion, comparison to the conventional age-based formula, the ultrasound-based approach by measuring the subglottic diameter had a better prediction percentage in estimating appropriate size of ETT in pediatric patients.

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ANNEXURE –I – CONSENT FORM

Master / /Miss. ________________________________we are requesting you to enroll you in the study titled **"COMPARISION BETWEEN ULTRASOUND BASED TECHNIQUE AND AGE BASED FORMULA IN PREDICTION OF APPROPRIATE ENDOTRACHEAL TUBE SIZE IN CHILDREN -"ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY"** conducted by Dr. ___________________ Post Graduate in M.D. Anaesthesiology under the guidance of Dr. ________________ Professor and Head Department of Anaesthesiology, J.N. Medical College, Belagavi under KAHER, Belagavi.

Respected Sir/Madam, we request you to participate in our study as you are eligible for it. During the study you will be asked some questions regarding your medical history and you are supposed to answer to the best of your knowledge.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N.Medical College. If you decide to participate you are free to withdraw at any time.

INTRODUCTION AND PURPOSE: The present study will be conducted among patients in the age group of 1-8 years scheduled for various elective surgeries under general anesthesia with endotracheal intubation at KLE's Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi. You are requested to participate in the study and your participation is completely voluntary and to compare the efficiency of ultrasound guided measured subglottic diameter with the age based formula for the estimation of size of the endotracheal tube intubation in patients undergoing general anesthesia.

PROCEDURE: If you agree to enroll in my study, I will ask your present, past and family history. Then you will be clinically examined in detail. You will be allotted into one of the two groups randomly using computer generated software.

Group A: ETT tube size will be estimated by using age based formula

In children < 6years - Age/3 +3.5

In children > 6years - Age/4+4.5

Group B: ETT tube size will be estimated by measuring the subglottic diameter using high resolution B ultrasonography sonosite M TURBO linear probe of frequency 7-15MHz.

BENEFITS: Patient will not be eligible for any kind of monetary benefits or free services by virtue of our participation in the study.

RISKS: Methods applied to the study are safe

COST OF PARTICIPATION: The cost of the investigation will be borne by the study subject. The other indirect expenses will be borne by the investigator.

PRIVACY AND CONFIDENTIALITY: The results of the study may be published in journals for scientific purposes. However, your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY: You can withdraw from the study at any time if you wish to do so.

ALTERNATIVES: The researcher may use the information gathered from this study for presentation in scientific meetings. However, your identity will not be revealed. Any information that is obtained in connection with this study and that can be identified with your identity will remain confidential.

PRIVACY AND CONFIDENTIALITY: The only people to know that you are as research subject are you and members of the research team. No information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

AUTHORIZATION TO PUBLISH RESULTS: When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remaining confidential.

FINANCIAL INCENTIVES FOR PARTICIPATION: No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

COMPENSATION: In the event of injury related to the study, treatment will be made available through KLES Hospital and MRC, Belagavi. There is no compensation or payment for such medical treatment by law. If you get injured you may contact Dr. ______________________ at Department of Anaesthesiology, J.N. Medical College or by Ph. No: ______________QUESTIONS: In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact Dr. ___________________ Department of Anesthesiology, J.N. Medical College, Belagavi. Phone number: _________________ or Dr. __________ Professor and head, Dept. Of Anaesthesiology, J.N. Medical College, Belagavi. If you have any queries about your rights as a study subject, you may call, DR. HARSHA HEGDE**,** Chairman, JNMC, IEC& Scientist, ICMR, National Institute of Traditional Medicine, Belagavi.

CONSENT STATEMENT TO PARTICIPATE IN RESEARCH STUDY

I Mr./Mrs.------------------ voluntarily agree for the participation of the subject for the study. By signing this consent form I am not giving up any of my legal right. I may withdraw from the study any time. I am signing the consent form after having read or been read to me in my vernacular language, including the risk and the benefits and having all my queries cleared.

Name of study patient: ____

Signature or the left thumb impression: ____________________________________

Name and signature of witness: ____

Name and signature of investigator: ____

Date:

Place:

ANNEXURE-II

PROFORMA

"COMPARISION BETWEEN ULTRASOUND BASED TECHNIQUE WITH AGE BASED FORMULA IN PREDICTION OF APPROPRIATE ENDOTRACHEAL TUBE SIZE IN CHILDREN - "ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY"

Group allotted: A □ B □ Date of Examination:

Name: Age:

Gender:

Address:

History and examination:

Weight: Clubbing:

Height: Pulse:

Temp: B.P.:

Pallor: RR:

Cyanosis: SPO2:

Pedal edema:

Drugs and past history:

Birth History:

H/o previous surgery/(s) where airway difficulty was encountered. Yes No

Allergy and previous anesthetic experience:

Cardio-vascular system:

Respiratory System:

CNS:

P/A:

Musculoskeletal system:

Teeth:

Jaw movements:

Airway assessment:

Spine:

Preoperative physical status ASA Grade I II III IV V

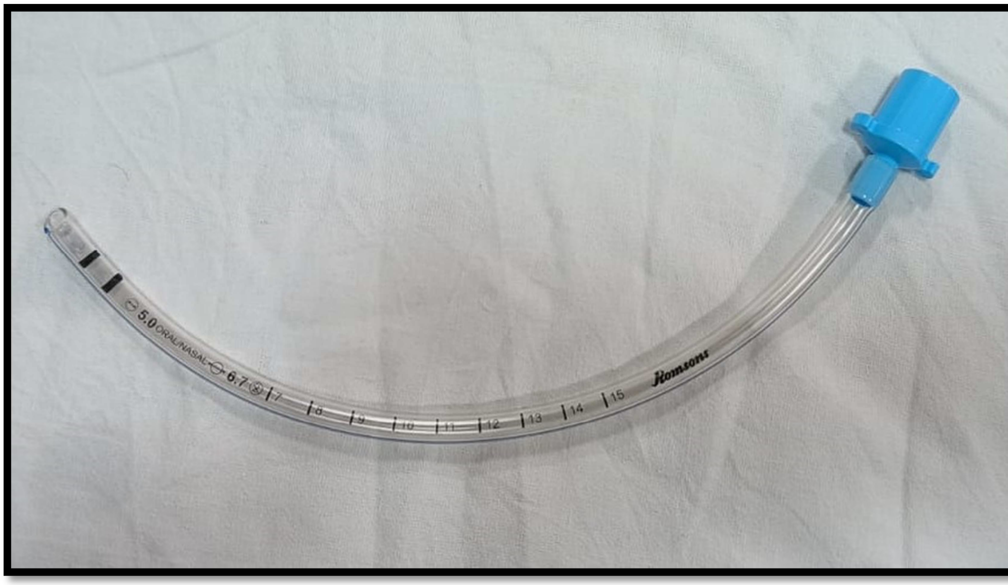
Proposed surgery:

Premedication:

	No of ETT changes		
Age Group (years)	**1**	**2**	**3**
1 – 3			
3 -6			
6 -9			

ANNEXURE III

PHOTOGRAPHS



Photograph 1: UNCUFFED ENDOTRACHEAL TUBE

Photograph 2: ULTRASONOGRAPHIC PROBE

PHOTO 3: USG PROBE PLACEMENT

PHOTOGRAPH 4: SUBGLOTTIC DIAMETER

ANNEXURE IV

MASTERCHART

Sl No	Randomisation Number	Patient Name	Age in years	Sex	ASA Grade	Weight (Kgs)	Actually put ETT	Age based formula	ETT changed	appropriate size
1	1	B/o laxmavva	2	female	I	8.8	5	4	yes	no
2	1	Vedant	4	male	I	11	5	5	no	yes
3	1	Sarshi	1	female	I	6.6	4	3.8	no	yes
4	1	Vinayak	8	male	I	21.5	5.5	5.5	no	yes
5	1	B/o Nagina	3.5	female	I	10.8	4.5	4.5	no	yes
6	1	B/o Malari	1	male	I	5	4	4	no	yes
7	1	Mohammad	6	male	I	15	5.5	5.5	no	yes
8	1	Ryan	8	male	I	22.5	5.5	6.5	yes	no
9	1	Joy	6	male	1	18	5.5	6	no	no
10	1	Nakul	2	male	I	7	4	4.1	no	no

11	1	Shivani	1.5	female	I	5	3.5	4	no	no
12	1	Arnav	6	male	I	15	5	6	yes	no
13	1	Rama	1.2	male	I	4.5	4	3.9	no	yes
14	1	kushi	4	female	I	9	5	4.8	no	yes
15	1	krishna	8	male	I	14	5.5	6.5	yes	no
16	1	advik	1	male	I	6	4	3.8	no	yes
17	1	fardik	4	male	I	20	5.5	4.8	no	no
18	1	prenika	8	female	I	20	5.5	6.5	yes	no
19	1	priya	3	female	I	14	4.5	4.5	no	yes
20	1	tanushree	7	female	I	19	6	6.25	no	yes
21	1	mallik	1	male	I	7	4	3.8	no	yes
22	1	akshay	7	male	I	15	6	6.25	no	yes
23	1	harshit	3	female	I	15	4.5	4.5	no	yes
24	1	samanvith	4	male	I	9	4	4.5	no	yes
25	1	riya	6	female	I	14	5	4.8	no	yes

Sl NO	Randomi sation Number	Patient Name	Age in years	Sex	ASA Grade	Weight (Kgs)	Actually put ETT	Ultrasound measured subglottic diameter	Corresponding ETT with external diameter (in mm)	Age based formula for outerdiameter tube	Age based Inner diameter	ETT changed	Appro priate size
1	2	Supriya	8	female	I	18	5.5mm	7.2	7.6	8.8	6.5	no	yes
2	2	Rohit	3	male	I		4.5mm	6	6.2	6	4.5	no	yes
3	2	Shivadeep	8	male	I	24	5.5mm	7.5	7.6	8.8	6.5	no	yes
4	2	Ashwanth	2	male	I	9	4.5mm	5.9	6.2	5.3	4	no	yes
5	2	Ganesh	8	male	I	20	6.0mm	8.1	8.2	8.8	6.5	no	yes
6	2	Shreya	5	female	I	20	5.0mm	6.7	6.9	6.7	5.1	no	yes
7	2	B/o Nirmala	1.5	male	I	7.5	4.5mm	5.7	5.7	5.3	4	no	yes
8	2	sharaddi	8	female	I	10.2	5.0mm	6.8	6.9	8.8	6.5	no	yes
9	2	Niranjan	4	male	I	6	5.0mm	6.8	6.9	6	4.8	no	yes
10	2	Rishika	2.5	female	I	3.5	3.5mm	4.3	4.8	6	4.3	no	no
11	2	Swapnil	5	male	I	15	5.0mm	6.5	6.9	6.7	5.1	no	yes
12	2	Sarita	1.5	female	I	7	4.0mm	5.4	5.5	5.3	4	no	yes
13	2	Yogesh	8	male	I	17	6.0mm	8	8.2	8.8	6.5	no	yes

14	2	Amrutha	8	female	I	20	5.5mm	7.5	7.6	8.8	6.5	no	yes
15	2	Samanvi	5	female	I	13	5.5mm	7.3	7.6	6.7	5.1	no	yes
16	2	Madhushree	2	female	I	5	5.0mm	6.7	6.9	5.3	4.1	no	yes
17	2	Ritesh	3	male	I	14	5.0mm	7	6.9	6	4.5	no	yes
18	2	Advik	1.5	male	I	5	4.0mm	5.3	5.5	5.3	4	no	yes
19	2	ishaan	7.5	male	I	14	6.0mm	8	8.2	8	6.3	no	yes
20	2	amaya	4	female	I	10	5.0mm	7.4	7.6	6	4.8	no	yes
21	2	dhruv	5	male	I	14	5.5mm	7.8	7.6	6.7	5.1	no	yes
22	2	akhila	4.5	female	I	14	5.0mm	6.6	6.9	6.7	5	no	yes
23	2	sheetal	3	female	I	9	4.5mm	6	6.2	6	4.5	no	yes
24	2	arjun	5	male	I	15	5.0mm	6.7	6.9	6.7	5.1	no	yes
25	2	rudra	2	male	I	6	4.5mm	6	6.2	5.3	4.1	no	yes