"ASSESSMENT OF CONVENTIONAL METHOD OF ENDOTRACHEAL TUBE INSERTION DEPTH USING ULTRASONOGRAPHY IN INDIAN ADULTS: A ONE-YEAR PROSPECTIVE OBSERVATIONAL STUDY"

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ENDORSEMENT

This is to certify that the dissertation entitled **"ASSESSMENT OF CONVENTIONAL METHOD OF ENDOTRACHEAL TUBE INSERTION DEPTH USING ULTRASONOGRAPHY IN INDIAN ADULTS: A ONE-YEAR PROSPECTIVE OBSERVATIONAL STUDY"** is a bonafide research work done by **(REG NO. BA0119013)** Department of Anaesthesiology, Jawaharlal Nehru Medical College, Nehru Nagar, Belagavi – 590 010.

DR. Rajesh. S. Mane MD, DNB
Professor and Head,
Department of Anaesthesiology,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

Dr. (Mrs)N.S. Mahantshetti
MD(paed)
Principal,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

PLAGIARISM CERTIFICATE

JAWAHARLAL NEHRU MEDICAL COLLEGE

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Nehru Nagar, Belagavi- 590 010, Karnataka, INDIA

0831 - 2471350 0831 - 2470759 www.jnmc.edu principal@jnmc.edu

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Dr. (Mrs:) N.S. Mahantashetti.
Chairperson-Antiplagiarism Committee &
Principal,
J. N. Medical College, Belagavi.

To,
Reg. No. BA0119013.
Postgraduate Student,
2019-20 Batch,
Department of Anesthesiology,
J. N. Medical College, Belagavi

LIST OF ABBREVIATIONS USED

ASA	-	American Society of Anaesthesiologists
BMI	-	Body Mass Index
BP	-	Blood Pressure
cm	-	Centimetre
CNS	-	Central nervous system
CVS	-	Cardiovascular system
ETT	-	Endotracheal tube
GIT	-	Gastrointestinal tract
Kg	-	Kilogram
MPG	-	Mallampatti grading
PR	-	Pulse rate
RR	-	Respiratory rate
RS	-	Respiratory system
VCD	-	Vocal cord-cuff Distance.

ABSTRACT

TITLE: Assessment of conventional method of endotracheal tube insertion depth using ultrasonography in Indian adults: a one-year prospective observational study.

BACKGROUND & AIMS: Endotracheal intubation is the most common procedure done for securing airway during elective surgeries under general anaesthesia. Malpositioning of tracheal tube can cause various complications. The tube can be placed too shallow, near the vocal cords or too deep, entering the right main bronchus. Both instances can have serious complications. Our study aimed to use ultrasonography to determine the distance from vocal cords to upper end of saline inflated endotracheal tube cuff and estimate the occurrence of shallow and deep intubations.

METHODS: A prospective observational study was conducted which included 68 patients aged 18-60 years, of either gender, belonging to ASA grades I and II, undergoing elective surgeries under general anaesthesia with tracheal intubation with cuffed ETT. Using a linear transducer with transverse orientation, the level of vocal cords(A) was marked before intubation. Tracheal tube was secured at 22cm in males and 20cm in females. The cuff was inflated with saline of 4-5ml. Using the linear transducer with longitudinal orientation, the proximal end of the cuff is marked(B). Distance between points A and B measured (vocal cord-cuff distance; VCD). The cuff was deflated and again filled with air.

RESULTS: The mean values of vocal cord-cuff distance (VCD) measured in males and females were almost similar and measured about 1.99cm. Two patients had a VCD <1.5cm

indicating shallow intubating and one patient had VCD>2.5cm indicating deep intubation. The percentages of shallow and deep intubations were 2.9% and 1.4% respectively.

CONCLUSION: Fixing the orotracheal tube at 22cm mark in males and 20cm mark in females ensures adequate depth of insertion as confirmed by measurement of distance of proximal end of saline inflated cuff from the vocal cords using ultrasonography with lesser likelihood of shallow or deep intubation. Hence, 22/20 rule is a reliable method of depth of insertion of orotracheal tube.

KEYWORDS: saline inflated endotracheal tube cuff, vocal cord-cuff distance.

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INTRODUCTION

Endotracheal intubation is the most common procedure done for securing airway during elective surgeries under general anaesthesia. Malpositioning of the tracheal tube can cause various complications. [1]

The tube can be placed too shallow, near the vocal cords or too deep, entering the right main bronchus. Both instances can have serious complications. When the tube is placed near the vocal cords, it can cause compression of the peripheral nerve precipitating hoarseness and/or vocal cord paralysis. If the tube is too shallow, there may even be accidental extubation or laryngeal irritation.

When the tube is placed too deep, it may pass the carina and enter the right main bronchus, resulting in endobronchial, single lung ventilation, rendering collapse of the contralateral lung and hypoxia, with hyperinflation of intubated lung precipitating a tension pneumothorax. [2]

Tracheal tubes have intubation guide marks (one or two) which aid in placing the tip of the tube in an adequate depth in trachea. These markings are colored in black and placed cephalad to the proximal end of the cuff. [3] The guide mark on endotracheal tube should coincide with the vocal cord for adequate depth of placement. [12]

Optimal insertion depth has been studied and a distance measuring 2 to 6 cm between the distal tip of the endotracheal tube and the carina has been considered appropriate. [4] The safe distance between vocal cord and proximal margin of saline inflated cuff has been found to be in the range of 1.5 to 2.5cm. [1]

Flexion and extension of head and neck can displace the endotracheal tubes causing one of the complications mentioned above. Hence, tube should be securely fixed at the angle of mouth and care should be taken while positioning patients for surgery. [5]

Studies have been done to ascertain the adequate depth of insertion of endotracheal tube. In Asian population, male population should have their tubes secured at the angle of the mouth at 22cm mark while females at 20 cm mark on the endotracheal tube. [6] Securing the tube at 23cm and 21 cm in males and females respectively have been proven to either stimulate the carina or enter right main bronchus.[10]

Different methods have been tried to confirm the placement and adequate depth of insertion of tube. Bilateral lung auscultation for equal air entry has been a routine practice for confirming adequate depth. Chest radiography has been used to confirm depth of insertion of tube. Utilization of ultrasonography has been on the rise. Ultrasound is used to detect tracheal tube placement by loss of snow-storm sign. [11] Ultrasonographic assessment of pleural sliding with respect to respiration has proven useful to confirm intubation. It has also been used to visualize the cuff of the tracheal tube by filling it with saline. [7]

In today's care, ultrasonography is increasingly in use. The ideal depth of insertion of endotracheal tube has been found to be 22 cm in male and 20 cm in female. [6] The commonest method of confirmation of endotracheal tube placement has been through auscultation. Although auscultation can rule out a deep intubation, shallow intubations are often missed out. In view of this, the study will be conducted on utility of ultrasonography as a standard procedure to confirm the position of endotracheal tube inserted by conventional method.

OBJECTIVE

To determine the distance between vocal cords and proximal end of saline inflated endotracheal tube cuff using ultrasonography and estimate the occurrence of shallow and deep intubations.

REVIEW OF LITERATURE

Optimal insertion depth of an endotracheal tube is necessary to avoid serious complications which may manifest immediately or post operatively. Many studies have been done to assess the adequate depth and confirm the depth of insertion.

There have been studies on effect of shallow intubation and deep intubation on vocal cord paralysis and endobronchial intubation respectively.

The use of marks on the endotracheal tube for optimal placement has been studied and used as a guide even today for adequate placement of tube.

The use of ultrasonography been increasing in the field of anaesthesiology. Airway ultrasound has been implicated for identifying cuff of the tracheal tube by filling it with saline.

In the year 1985, John W. Cavo had conducted a cadaver study to find out the possible area of vulnerability of the recurrent laryngeal nerve and the tracheal tube cuff changes under the effect of anaesthetics and suggested means to prevent true vocal cord paralysis post intubation. Dissection of 10 cadaveric larynxes revealed that anterior branch of the nerve in subglottic region is the most vulnerable site to compression. Using a mixture of anaesthetic gases to inflate the cuff helped in preventing paralysis of the nerve. This study also demonstrated that a mark made on the endotracheal tube about 1.5 cm cephalad to the proximal end of the cuff and placed at the level of true vocal cords during intubation ensured safety of the nerve from compression. [8]

Robert L. Owen and Frederick W. Cheney in 1987 hypothesized that measurements present on the endotracheal tube could be used as a reference for inserting the tip of endotracheal tube in relation to the carina. The research consisted of a study group of 304 participants and a control group of 263 participants. The range of height in men was taken

as 168-184cm and 158-174cm in women. In the study group, the tube was placed at 23cm mark at upper incisor in men and 21cm mark in females. In control group, the tube was fixed based on auscultation of chest. Chest radiograph was used to evaluate the position of the tube in relation to the carina. The study revealed seven right endobronchial intubations, eight intubations less than 2cm from the carina among the control group. In study group however, only two intubations lesser than 3cm from carina, and no right endobronchial intubation. Thus, referring the marks on side of the tube prevented the occurrence of endobronchial intubation more than bilateral chest auscultation. [2]

In 1991, S. Mehta from Burnley General Hospital, Lancashire designed a study to observe whether guide marks placed appropriately proximal to the cuff helped in placement of the tube tip in the middle one third of trachea. Out of 140 adult patients belonging to ASA 1 or 2, aged 24-80 years, patients were intubated with TFX orotracheal tube or Portex tubes with 8.0mm internal diameter for men and 7.0mm for women. The TFX tube included a circular guide mark of width 2mm which was 3cm proximal to the cuff on 8.0mm tubes and 2.75cm on 7.0mm tubes. Portex tubes had a guide mark placed over one fourth of the tube circumference and 3cm from the proximal end of the cuff. The study confirmed the reliability of guide marks for intubation, whereby the tip of the tube was 3.7 to 4.1cm above carina. Thus, it was recommended that the guide mark should be 2.5cm in male and 2.25cm in female from the proximal end of the endotracheal tube cuff. [3]

Despite adequate length of tracheal tube insertion, manipulation of head and neck during surgery can displace the tube, so the extent of allowable displacement had to be ascertained. R. Hartey and I.G. Kestin in 1995 compared the extent of displacement of oral and nasal endotracheal tubes in the same patient during manipulation using a fibreoptic bronchoscope. The tubes moved about 15mm towards carina on flexion of head and neck and 8.5mm away from carina with extension of head and neck. A guide mark placed 3cm

cephalad to cuff and 8cm cephalad to distal end of tube ensured optimal placement of tube despite movement induced displacement of tube. [5]

The concern about correctly placing the tip of the tube is to ensure a safe distance from the carina to prevent endobronchial intubation. Various studies have used fibreoptic bronchoscope to determine the optimal length of tracheal tube. Manu Varshney et al. measured airway distances using fiberoptic bronchoscope in Indian population to find a correlation between length of tube and height of the patient. They found a strong correlation between the two and concluded that airway distances were shorter in Indian population, thus fixing at 23cm and 21cm in males and females respectively would be too close to the carina.[10]

Later in 2013, Shingo Mitsuda et al. conducted a retrospective study in Japanese adult patients undergoing oral endotracheal intubation using the vocal cord marker. They determined the distance between the tip of the tube and carina(T-C) by portable chest radiography at the end of surgery and compared it with the same distance measured if tube insertion was done using 22/20cm rule. The study revealed the depth of insertion to be appropriate if T-C length is 2-6cm, shallow if >6cm and deep if <2cm. However, three females who were shorter than 150cm required fixation of tube <20cm mark to avoid endobronchial intubation. [4]

Shashi Kumari et al. conducted a cross-sectional observational study on 92 Indian adult patients and found out with fiberoptic bronchoscopic measurements that placing the tube using the guide mark was safer than following 23/21cm rule for fixing the tube in males and females respectively as the latter carried risk of carinal impingement or accidental endobronchial intubation. [12]

The ideal length of endotracheal tube was validated in Asian population compared to Western standards. The standard depth of insertion for Caucasian population was 23cm

for males and 21cm for females. Amos Lal et al. conducted a retrospective study in the Intensive Care Unit which included 708 patients from Asian population. They used Chest x-ray information to confirm the tube position. Distance of 2-5cm from carina was considered acceptable, while >5cm and <2cm was considered out of the acceptable range. The study suggested that males and females belonging to South East Asian population should have their tube secured by 1cm lesser than western standards which is 22cm for males, and 20 cm for females. [6]

The use of ultrasound imaging for visualization of endotracheal tube cuff is emerging. It can be safely used in pregnant women, patients requiring frequent confirmation of tube placement and patients in Intensive Care Unit (ICU). It has become a good alternative to chest radiography. In 1987, Raphael and Frederick were one of the firsts to use airway ultrasound to view the endotracheal tube cuff in a longitudinal view. They used foam cuffed tubes and saline filled polyvinyl endotracheal tubes and tried to visualize the cuff using a real-time B mode ultrasound imaging with a linear transducer of 3.5Hz. The cuffs were better seen in the sagittal view, which was enhanced with a longitudinal to-and-fro movement. They could also reposition a distally placed tracheal tube under ultrasound guidance. [9]

Bilateral chest auscultation has been a conventional method to confirm positioning of tube. Nandita Kad et al. conducted a prospective observational study in Rohtak which included one hundred patients posted for surgery under general anaesthesia. Their aim was to confirm position of tracheal tube using point-of-care ultrasonography (POCUS) and auscultatory method. Ultrasonic assessment consisted of tracheal dilation visualized with probe placed transversely and pleural sliding due to lung expansion with ventilation visualized with probe placed longitudinally on the anterior aspect of the third intercostal space at midclavicular line bilaterally. Tracheal dilatation seen on ultrasound showed to

be 100% accurate. This helped in identifying accidental oesophageal intubation. Pleural sliding and tracheal dilation showed to be more sensitive and specific than standard auscultation. [7]

Endotracheal tube can also be detected by the disappearance of snow-storm sign in trachea on ultrasonography. Vijaya Patil et al. conducted a study based on this concept and proved the usefulness of ultrasonography in rapid assessment of correct tracheal intubation with a sensitivity of 96%, specificity of 100% and an accuracy of 96%. [11]

Xuanling Chen at al. conducted a prospective case-control study on 105 Chinese adults to verify the correct depth of insertion of endotracheal tube using ultrasonography. Patients were intubated using 23/21cm rule using a videolaryngoscope. They used a linear transducer of 6-13 MHz to visualize the vocal cords by placing the probe transversely. With the probe held longitudinally, cuff was identified by inflating it with about 8 mL of saline keeping the cuff pressure within 30cm H_2O. The level of vocal cord and proximal end of cuff were marked on the skin and distance between the two calculated. The safe distance was considered to lie in the range of 1.5-2.5cm. The study proved to be a feasible and reliable method of confirming the depth of insertion of ETT. [1]

BASIC SCIENCES

ANATOMY OF THE AIRWAY

EMBRYOLOGY

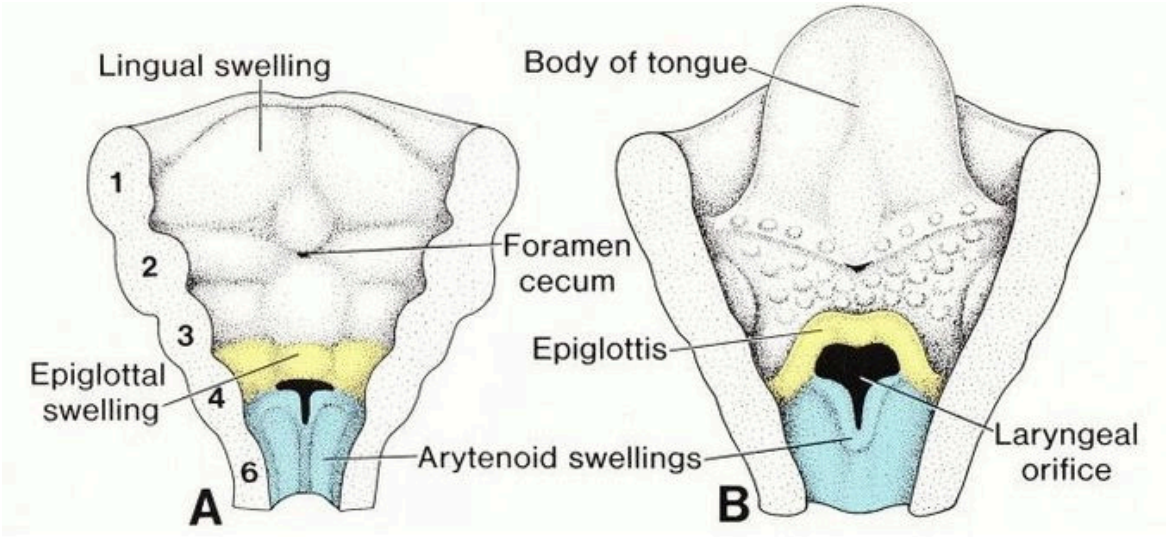


Figure 1. Development of laryngeal cavity from laryngotracheal groove.

Around fourth week of embryological life, a laryngotracheal groove develops along the ventral aspect of pharynx. Eventually, the edges of the groove fuse and form a splanchnopleuric laryngotracheal tube. The fusion is more profound caudally while cranially it remains open, in continuity with pharynx. The caudal end gives two lateral pouches which form the precursors for bronchi and lung buds. The cranial end gives rise to the larynx and trachea. The respiratory tube is lined with endoderm, while the splanchnic mesenchyme from pleural coelom gives rise to the connective tissue, cartilages and smooth muscles. The laryngeal cavity is initially T-shaped with arytenoid swellings. As the epithelium of larynx develops, it temporarily occludes the lumen and re-canalizes by the tenth week of embryological life. The third, fourth and sixth branchial arches give rise to the laryngeal cartilages. The larynx is supplied by superior and recurrent laryngeal nerves which are derived from the fourth and sixth branchial arches respectively. [13]

CARTILAGES OF LARYNX

By evolution, larynx served as a protector of upper airway from aspiration, later developed into an organ of phonation. It lies against the cervical vertebrae C4-6.

Various cartilages, ligaments and muscles together form the structure of larynx.

Cartilages: Thyroid, epiglottis, cricoid, arytenoid, corniculate and cuneiform.

Ligaments: Thyrohyoid, cricothyroid, cricotracheal, hyoepiglottic membrane.

Muscles: Extrinsic- Sternothyroid, thyrohyoid, inferior constrictor.

Intrinsic- Posterior cricothyroid, lateral cricothyroid, interarytenoid, thyroarytenoid, vocalis and cricothyroid. [14]

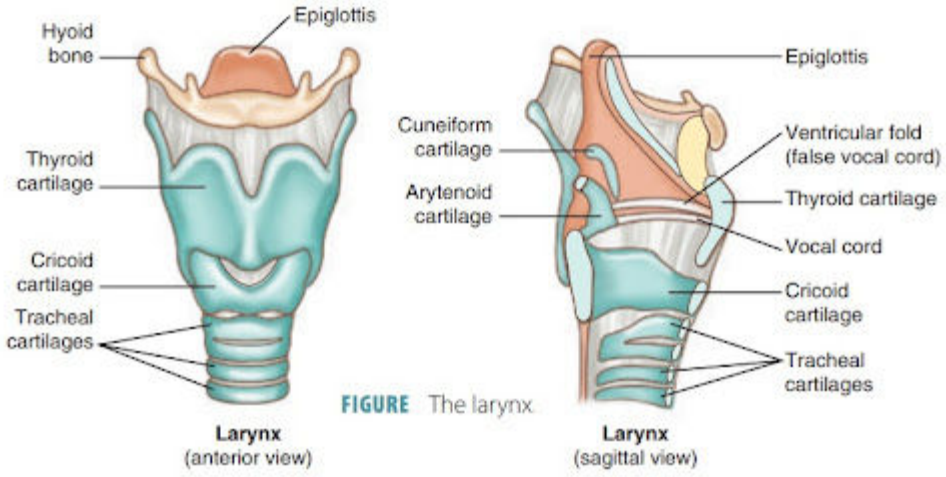


Figure2: Cartilages of the larynx: anterior and sagittal views.

THYROID: Largest laryngeal cartilage and shaped like a shield with two laminae joining inferiorly in midline to form a prominence commonly known as the Adam's apple which is more prominent in males. The laminae have each one superior and one inferior horn for articulation with other cartilages.

CRICOID: The only cartilage which forms a full circle within the trachea, shaped like a signet ring. Lying against C6 vertebra, it forms an arch anteriorly and widens posteriorly as a lamina. Cricoid articulates superiorly with inferior horn of thyroid and arytenoid.

EPIGLOTTIS: Shaped like a leaf, it is linked to the thyroid through the thyro-epiglottic ligament. The mucous membrane of upper part continues with that of the tongue and oropharynx forming the median and lateral glosso-epiglottic folds respectively between which lie the valecullae, a dangerous site for sharp objects like fish bones to get impacted. The hyo-epiglottic ligament links the lower part to the hyoid bone. Neonates have floppy epiglottis to protect the airway while suckling.

ARYTENOID: They are paired pyramid shaped cartilages lying on the posterior aspect of cricoid. They each have a lateral process for muscular attachment and anterior process for the vocal ligament to attach to in its posterior aspect.

CUNEIFORM (Wrisberg cartilages): These are paired cartilages present on either side of aryepiglottic fold, supporting the vocal folds and epiglottis in its lateral aspect.

CORNICULATE (Cartilage of Sanotrini): They are small, nodule-like, paired cartilages each lying on the apex of an arytenoid.

EXTRINSIC LIGAMENTS: Attach larynx to hyoid or trachea.

a. Thyrohyoid: Between upper part of thyroid to posterior aspect of hyoid.
b. Cricotracheal: Between cricoid and first ring of trachea.
c. Hyoepiglottic: Between upper aspect of hyoid and epiglottis.

INTRINSIC LIGAMENTS: Connections within the larynx.

a. Cricothyroid membrane: Shaped like a pyramid, its apex lies on the thyroid cartilage and base lies on the cricoid in its superior border.

b. Cricocorniculate: Between cricoid and corniculates.
c. Thyroepiglottic: Between thyroid and epiglottis.
d. Thyroarytenoid: Between the arytenoid and middle portion of thyroid. The ligament is subdivided into superior and inferior ligaments in relation to vocal cords.
e. Arytenoidepiglottic: Between arytenoids and epiglottis.

MUSCLES OF LARYNX: They have three functions which include closing the airway passage while swallowing, opening the inlet during respiration and aiding in phonation.

a. Abductors: Posterior cricoarytenoids.
b. Adductors: Lateral cricoarytenoids, interarytenoid.
c. Tensor: Cricothyroid.
d. Relaxor: Thyroarytenoid.
e. Fine adjustment: Vocales

LARYNGEAL CAVITY

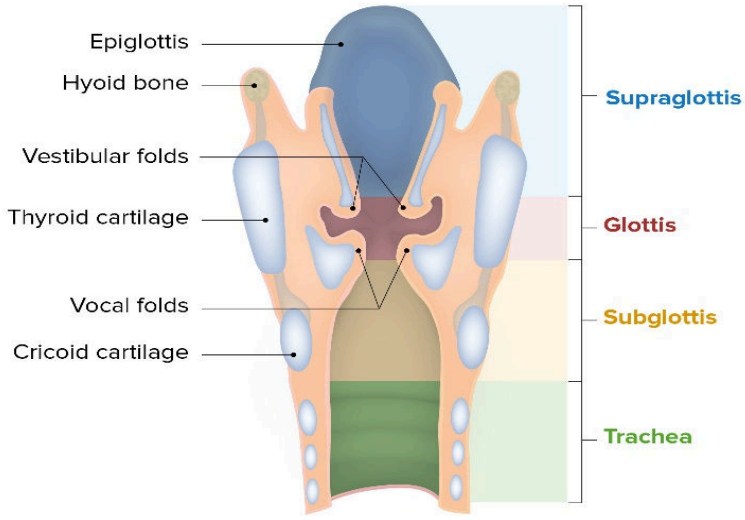


Figure 3: Boundaries of the laryngeal cavity.

Extends from the inlet of larynx to the lower part of cricoid. It is shaped as an inverted pyramid, with its oval base facing the tongue, apex into the trachea, two lateral parts and one posterior part. The lateral aspects consist of superior thyroid, middle cricothyroid and inferior cricoid parts. The posterior part of the cavity is a part of the anterior aspect of pharynx, consisting of two vertical recesses called piriform sinuses. The middle portion of laryngeal cavity, called glottis, divides the cavity into supraglottic, glottic and infraglottic regions. The glottic space is comprised of vocal cords, glottis and ventricles of larynx. The vocal cords are four in number, two lying superiorly and two inferiorly. They attach to thyroid anteriorly and arytenoid posteriorly. The superiorly lying cords are relatively thin and devoid of muscles hence referred to as false vocal cords while the inferior folds comprise of muscles which aid in adduction, hence referred to as true vocal cords. Ventricles of larynx (Morgagni sinus) are present between false and true vocal cords. [14]

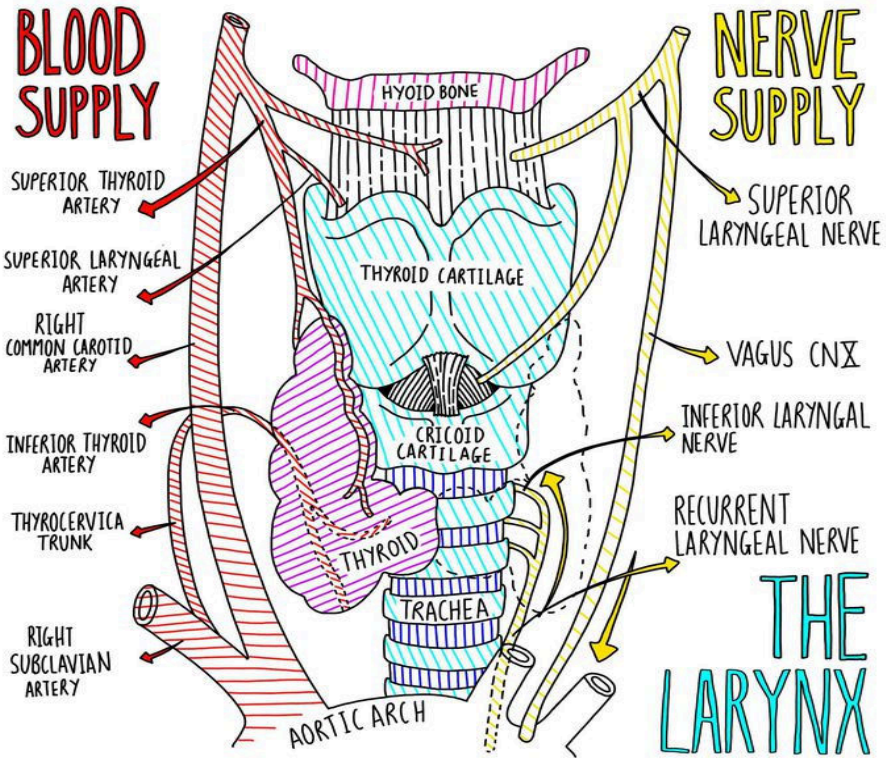


Figure 4: Blood supply and Nerve supply of the larynx.

BLOOD SUPPLY

The external carotid artery gives the superior thyroid artery and the thyrocervical trunk gives the inferior thyroid artery. These two arteries give superior and inferior laryngeal branches and superior thyroid gives cricothyroid branch. From epiglottis to superior vocal cords, the superior laryngeal artery supplies while for inferior vocal cords and below, the supply is inferior laryngeal artery.

The veins accompany the arteries and hence named after the same. They eventually drain into subclavian and internal jugular veins via inferior and superior thyroid veins.

LYMPHATIC DRAINAGE

Two groups of lymphatics namely supraglottic and infraglottic are present. The denser supraglottic and subglottic lymphatics drain ultimately into deep cervical nodes. The vocal cords do not have lymphatic drainage.

NERVE SUPPLY

a. Superior Laryngeal Nerve (SLN): It is a branch of tenth cranial nerve Vagus from its inferior ganglion. It divides into internal and external laryngeal nerves beneath the hyoid. While the external branch innervates cricothyroid, the internal branch runs caudally along the thyrohyoid membrane supplying the mucosa of laryngeal inlet.
b. Inferior Laryngeal Nerve or Recurrent Laryngeal Nerve (RLN): It supplies all the intrinsic muscles excluding cricothyroid. The left RLN takes origin from vagus in the thorax, loops around aortic arch and then runs cranial to the trachea and finally enters larynx. The right RLN originates at neck base, loops around the right subclavian artery and then runs cranial to trachea finally entering the larynx. [13]

ENDOTRACHEAL TUBES

Endotracheal tube is an equipment which is placed in the trachea to deliver gases and volatile agents to and from the lungs.

Resistance and work of breathing depend on the following:

- Internal diameter: directly proportional to the thickness of the tube.
- Length: directly proportional to length.
- Configuration: curves in the tube or connector increase resistance, so does kinking.

The endotracheal tube and connector constitute mechanical dead space although since they are usually less than that of the natural passages, it is reduced by intubation.

Material of the tube:

- Red rubber: can be cleaned, sterilized and suitable for using multiple times. But they are not transparent, they harden and become sticky with age, have poor resistance to kinking, become clogged by dried secretions more easily than plastic tubes, and pose a risk of latex allergy.

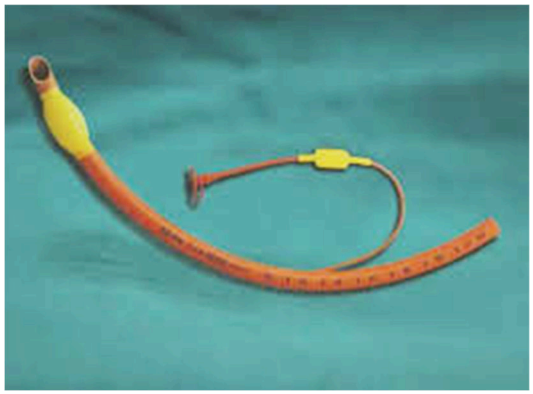


Figure 5: Red rubber tube.

- Polyvinyl Chloride (PVC): most widely used in disposable tracheal tubes. Compatible with tissues and relatively inexpensive. They are less prone to kinking, soften at body temperature. They are usually cooled prior to intubation to make it more firm and

warmed to aid in placement over a fiberscope. Smooth surface of these tubes makes it easier to pass suction catheter or bronchoscope. Tidal movement of respiratory moisture as well as materials in the lumen can be seen through the transparent tube.

Figure 6: PVC tube.

- Silicone: More expensive but can be sterilized and reused.

Figure 7: Silicone tube.

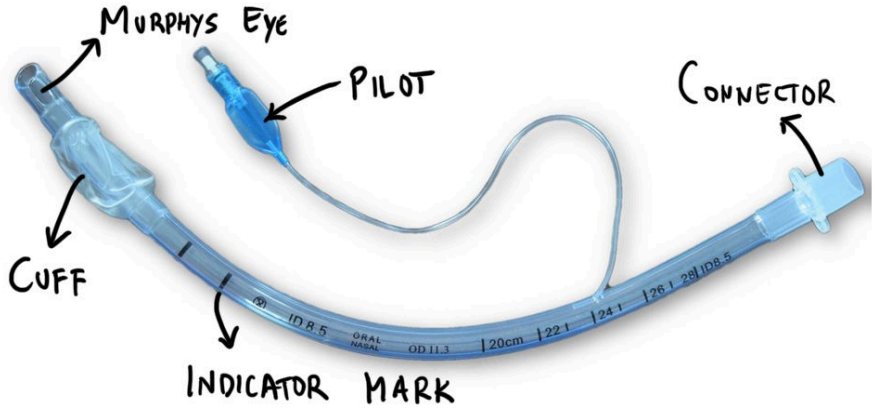


Figure 8: Parts of a regular endotracheal tube.

The machine end of the tube receives the connector and projects from the patient. This end of the tube can be shortened. The patient or the distal end is inserted into the tracheal. The slanted portion of the tip is called the bevel. The acute angle between the bevel and longitudinal axis of the tracheal tube constitutes the angle of the bevel. The opening of bevel faces to the left while viewing the tube from its concave aspect. This is because the tube is introduced from the right, and larynx is easier to visualize with the bevel facing to the left.

MURPHY EYE:

- The endotracheal tubes usually have a murphy eye, which is a hole through the tube wall opposite to the side of bevel.
- The advantage of murphy eye is that it provides an alternative pathway if the bevel becomes occluded. It also reduces trauma during nasal intubation.
- Tubes which lack murphy eye are called Magill or Magill-type tubes. The cuff can be placed closer to the tip in such tubes, thereby reducing the chances of accidental bronchial intubation.

TUBE SIZE:

- Size of the tube is designated by the internal diameter of tube in millimeters.
- According to ASTM standards, the tube size should be marked between the cuff and take-off point of the inflation tube for cuffed tubes.
- For uncuffed tubes, the size marking is towards the patient end.
- Sometimes, tube size is also marked on the pilot balloon so that the size can be determined when the tube is in place. [15]

TUBE MARKINGS

According to ASTM standards,

- The word nasal or oral or nasal/oral to be mentioned.
- Size of tube in internal diameter in millimeters, which may be marked on pilot balloon as well.
- For tubes 6 and smaller, outer diameter should be mentioned.
- Manufacturer or supplier name or trademark should be mentioned.
- Marking showing distance from patient end in centimeters. This helps in determining and monitoring the depth of insertion.
- Cautionary notes such as “Single use only” or “Do not reuse” to be mentioned if tube is disposable.
- Radiopaque marker should be mentioned at patient end or along the whole length of tube.

Some tubes have guide marks which aid in placing the tube with respect to the vocal cords.

CUFF SYSTEM

- ✓ Consists of a cuff, pilot balloon, an inflation tube and an inflation valve.
- ✓ Seals the trachea to prevent aspiration, avoid leakage of gas and ensures the tracheal tube is in the centre.

CUFF: It is inflatable, made of strong material, resistant to tear. It can be a low-volume, high-pressure cuff or high-volume, low-pressure cuff or foam cuff.

LOW-VOLUME HIGH-PRESSURE CUFF

- Small resting diameter.
- Makes the tracheal contour the same as the shape of the cuff.

- Requires higher pressure to seal the cuff with trachea.
- Protects from aspiration better and is visualized better while intubating.
- Post-operative sore throat lesser.
- Reusable and inexpensive.
- Can ensue ischemia of tracheal wall due to the lateral pressure exerted for a long duration.
- Not suitable for prolonged surgeries and postoperative ventilation with tube left in-situ.

HIGH-VOLUME LOW-PRESSURE CUFF

- Larger diameter at rest.
- As the cuff is inflated, it molds to the surface of trachea.
- Intracuff pressure is variable during spontaneous and controlled ventilation.
- As long as the wall of the cuff is not stretched, intracuff pressure and pressure on wall of trachea remain similar thereby helping in regulation of pressure applied on tracheal wall.
- Higher incidence of sore throat.
- Ineffective in preventing aspiration even at higher intracuff pressures.

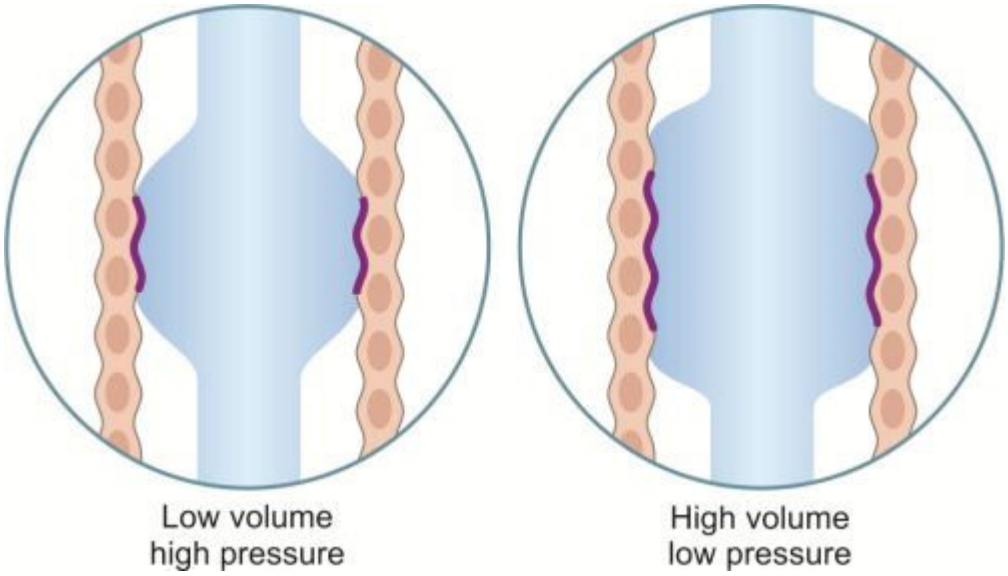


Figure 9: Cuff system.

LANZ CUFF (McGinnis balloon system)

- Consists of a plastic sheath which is transparent and contains a pilot balloon of latex material of high compliance and an automatic pressure-regulating valve between the pilot balloon and cuff.
- Both cuff and balloon get inflated parallelly while injecting air.
- When the pilot balloon is inflated to a level of causing the trachea to expand, air flows to the cuff from balloon.
- A quick loss of cuff volume into balloon is prevented by the pressure-regulating valve, which also found to be effective in protecting tracheal wall from increased cuff pressure due to diffusion of nitrous oxide.

CUFF PRESSURE

- Ideal intracuff pressure is the one that does not jeopardize the tracheal circulation or cause excessive dilation.
- Desirable range: 25-34 cm H_2O in normotensive adults.

- Higher intracuff pressures can ensue tracheal injury and ischemia.
- Lower pressure risks aspiration, eccentric positioning of tube and leakage.
- Cuffs filled with saline or water produce more stable pressure although the initial adjustment of pressure is difficult, and the cuff cannot be rapidly deflated.

Figure 10: Cuff monitoring system.

INFLATION SYSTEM

1. Inflation lumen is present within the endotracheal tube.
2. External inflation tube lies external to tube at an acute angle within 2.5mm diameter and is at least 3cm from the machine end of tube.
3. Pilot balloon acts as an external reservoir and is an indicator of cuff inflation.
4. Inflation valve prevents leak of gas from cuff after inflation. Absence of it requires clamping of inflation tube.
5. Tracheal tube connector has a patient end and machine end. It sometimes has a port for sampling respiratory gas.

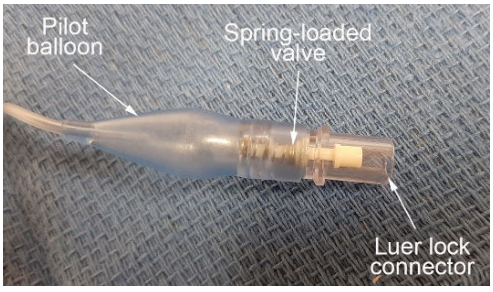


Figure 11: Cuff inflation system.

TRACHEAL TUBE CHOICE

1) Cuffed or Uncuffed:
    i) Cuffed tubes are commonly used in adults. They offer better seal to trachea and decrease aspiration risk but in children it may produce increased pressure on mucosa or injure the vocal cords and since the subglottic region is narrower than glottis, a smaller sized tube has to be used.
    ii) Uncuffed tubes are used in younger pediatric age group. Some amount of leak between the tube and tracheal wall should be present at higher airway pressures in order to avoid excessive pressure on tracheal mucosa.

2) Size: The lesser the diameter, more the ease of insertion of tube, higher the resistance, greater the difficulty to pass a suction catheter. Tubes of sizes larger and smaller than the desired should also be kept.

TUBE CHECK

- The tube should be checked for any splits, holes or obstructions.
- The cuff should be checked by inflating it and removing the syringe to rule out leaks in the valve. The inflated cuff should be checked for one minute for leakage.
- In case of sponge cuffs, they should be deflated completely, and the inflation tube clamped. Cuff is expected to remain deflated, if it inflate, the tube should not be used.

TUBE INSERTION TECHNIQUES

1. Oral intubation
    a. Oral intubation by direct laryngoscopy.

b. Blind oral intubation.

c. Intubation with Bougie.

d. Intubation using video laryngoscope.

2. Nasal intubation

a. Direct laryngoscopy.

b. Flexible fiberoptic laryngoscopy.

DEPTH OF INSERTION

- The ideal depth is when the cuff lies 2.25-2.5cm caudal to the vocal cords.
- Guide mark may be present cephalad to cuff for placement of tube correctly.
- In adults, the tube is fixed at 23cm mark against the upper incisor in males and 21cm mark in females.
- An extra 5cm depth is to be added for nasal intubation.

Figure 12: Guide mark seen on endotracheal tube.

GUIDE MARKS ON ETT: These marks aid in positioning the tube with respect to the cords. [15]

ULTRASONOGRAPHY IN AIRWAY

Ultrasonography has been used in medical field as early as 1940. The advantage of being a noninvasive diagnostic tool has increased the preference for it over other modalities. Anaesthesiologists have been using ultrasound in operating room and intensive care units. It gives real-time image and is radiation-free.

Ultrasound has proven to be efficient in airway management i.e., prediction and management of difficult airway, rapid assessment of the anatomy of airway.

Physics of ultrasonography: Ultrasound waves are mechanical waves which humans cannot hear under normal conditions, thus above a frequency of 20 kHz, in medical practice ranging between 2.5 to 10 MHz. A piezoelectric effect is produced by the material of the ultrasound probe. These piezo-crystals are usually lead-zirconate-titanate-based. The thickness of piezoelectric ceramic plates determines the transducer's frequency. At a lower frequency, the penetrance of tissues is higher with lesser potential image resolution. Usually, two types of transducers are used- linear and curved. [16]

- Linear:
    - ✓ higher frequency (5-14 MHz), better resolution.
    - ✓ visualization of superficial structures such as epiglottis, vocal cords, arytenoids, cricoid, cricothyroid membrane and trachea.
- Curvilinear(convex):
    - ✓ Frequency of 4-10 MHz, more penetrance.
    - ✓ Visualization of deeper structures such as base of tongue.

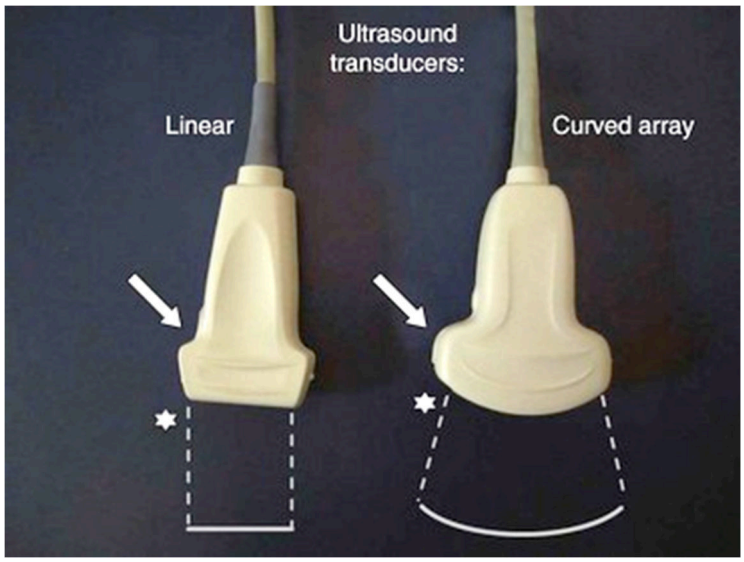


Figure 13: Ultrasound transducers.

The shape and internal architecture of a tissue is brought about by absorption, scatter, reflection, refraction and transmission of sound. Acoustic impedance is defined as the property of the tissue determined by amount of echo returned after hitting the tissue interface.

- Bones (mentum, mandibular rami, hyoid bone, sternum): hyperechoic (bright white)
- Cartilages (thyroid, cricoid): homogenously hypoechoic
- Muscles: hypoechoic, hetertogenous striated appearance
- Nerves: honeycomb or pepper pot like appearance with hypoechoic spots surrounded by hyperechoic background
- Fat and glands (submandibular, thyroid): homogenous, mildly to strongly hyperchoic compared to adjacent tissues.
- Fluid: anechoic
- Air: poor medium, reflects at air-tissue interface. Air-mucosa (A-M) interface has a bright hyperechoic linear appearance.

Different transducer orientation in the neck:

- Sagittal: longitudinally, midline
- Parasagittal: longitudinally, lateral to midline
- Transverse: across anterior surface of neck, transversely

Approaches of airway ultrasound:

- Transcutaneous: used to examine upper airway from floor mouth to sternal notch, and parasternal structures using any of the above orientations.
- Transoral or sublingual: probe-tissue contact excellent without producing gag reflex. Disadvantages include inability to use in pediatric and uncooperative patients, uneasiness of probe under tongue, hardly used by anaesthesiologists. [16]

TONGUE and FLOOR OF MOUTH: Visualized better with low frequency curvilinear probe in sagittal or transverse plane. Appears as hyperechoic structure.

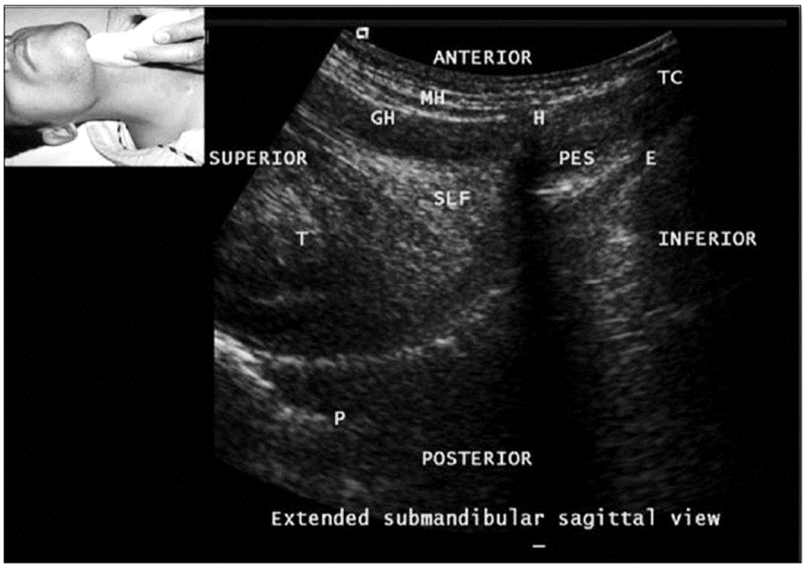


Figure 14: T: Tongue and floor of mouth on sagittal view.

HYOID BONE: On transverse view- hyperechoic inverted U-shaped linear structure. On sagittal, parasagittal and extended submandibular views- narrow hyperechoic curved structure casting an acoustic shadow.

EPIGLOTTIS: On parasagittal view- hypoechoic curvilinear structure and on transverse view- inverted C. Pre-epiglottic space (hyperechoic due to presence of fat) can be visualized anterior to the epiglottis. [17]

VOCAL CORDS: Deniated medially by vocal ligaments which appear hyperechoic. False cords lie parallel and above true vocal cords, are more hyperechoic, but relatively immobile during phonation as opposed to the true cords which oscillate and move towards the midline. Fluid interface using a water bath between the 3D probe and skin aids in better visualization of vocal cord movement. [18]

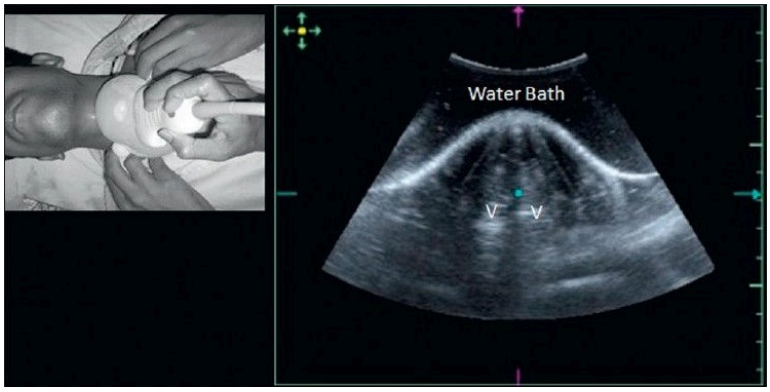


Figure 15: Vocal cords visualized with fluid interface.

CRICOID CARTILAGE and CRICOTHYROID MEMBRANE: Cricoid- On parasagittal view-oval, hyperechoic appearance; transverse view- seen as a hump.

Cricothyroid membrane- hyperechoic band connecting hypoechoic thyroid and cricoid cartilages.

TRACHEA: T1, T2 and T3 tracheal rings have a hyperechoic appearance. On parasagittal and sagittal views- “string of beads” appearance, on transverse view- inverted U highlighted by a linear hyperechoic A-M interface.

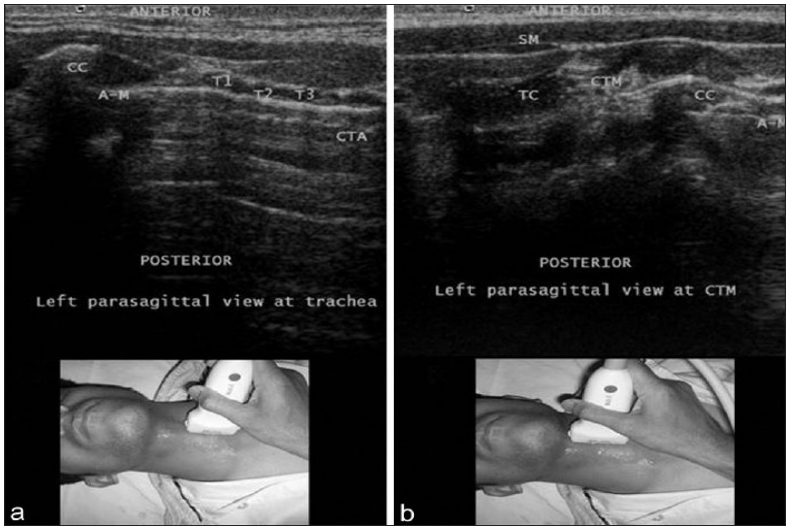


Figure 16: Left parasagittal view at trachea showing tracheal rings T1, T2, T3 and at cricothyroid membrane.

THYROID GLAND: On transverse view- seen lying anterolateral to trachea. Structures lateral to gland such as esophagus, vertebral bodies and internal carotid artery can also be seen on oblique transverse view.

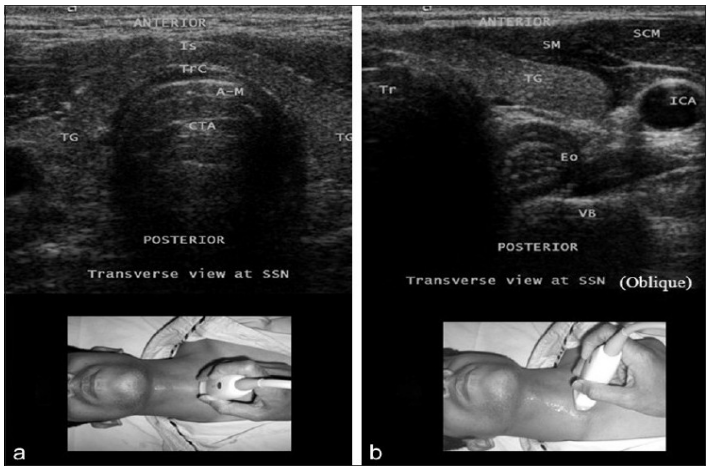


Figure 17: Transverse view at suprasternal notch. TG: thyroid gland, Eo: esophagus.

OESOPHAGUS: Made easier by asking patient to swallow. Seen to lie posterolateral to trachea at the level of suprasternal notch on oblique transverse view. [17]

CLINICAL APPLICATIONS OF AIRWAY ULTRASONOGRAPHY:

- **Confirmation of endotracheal intubation:** Useful in patients with cardiopulmonary arrest, bronchospasm, pulmonary embolism or technical difficulties with capnography. Trachea is seen as a curvilinear hyperechoic structure with shadowing and comet tail artefact, which increases when tube is within the trachea. A 'double tract' sign is seen in esophageal intubation. Lung sliding sign bilaterally on mechanical ventilation also confirms endotracheal intubation.

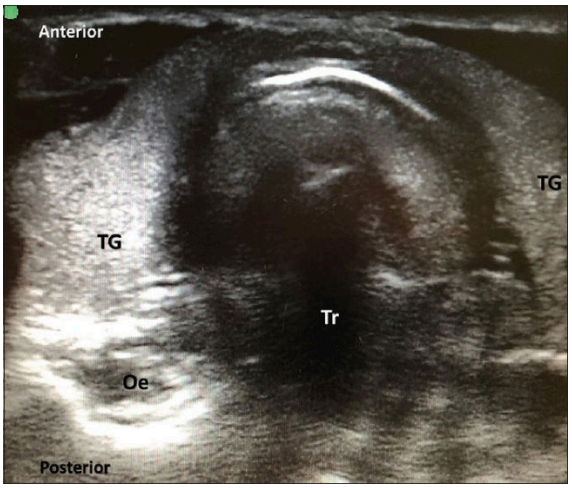


Figure 18: Tr: trachea, Oe: oesophagus. Endotracheal tube visualized within trachea.

Confirmation of correct tracheal tube depth: The ETT cuff is usually inflated with saline instead of air to facilitate better visualization on ultrasonography. This has proven useful in confirming the depth of ETT in pediatric population and pregnant women.

- **Prediction of the endotracheal tube size:** The diameter of subglottic area can be measured and is useful in predicting the size of tube especially in pediatric population as the subglottic area is the narrowest portion in them. Ultrasonography has been found to be superior to formulae-based size prediction while also preventing multiple attempts of intubation.

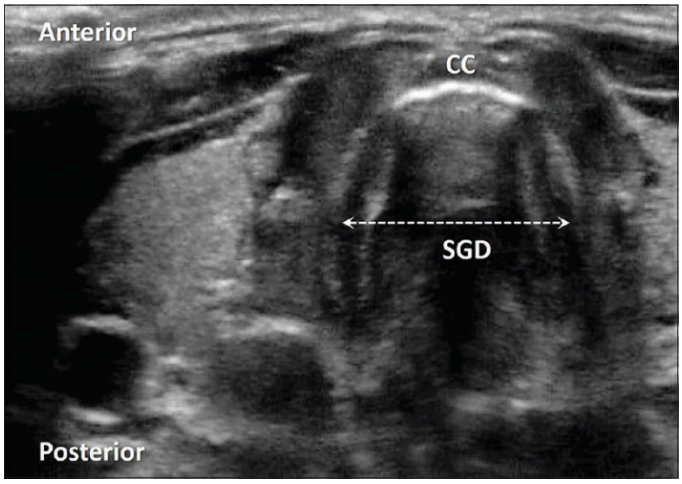


Figure 19: SGD: subglottic diameter.

- **Detection of endobronchial intubation:** Endobronchial intubation results in one lung ventilation which can be detected by presence of diaphragmatic movement and lung-sliding on ventilated lung and absence of the above on the contralateral lung.
- **Prediction of size of double-lumen tube (DLT):** The width of outer trachea at a level just above the sternoclavicular joint has been used to determine the size of DLT required. This method has been correlated well with CT measurement of tracheal and bronchial diameter.
- **Visualization of vocal cords:** Ultrasonography aids in easy visualization of vocal cords, especially for assessing superior and recurrent laryngeal palsies preoperatively in thyroid cancers and postoperatively in thyroidectomy.

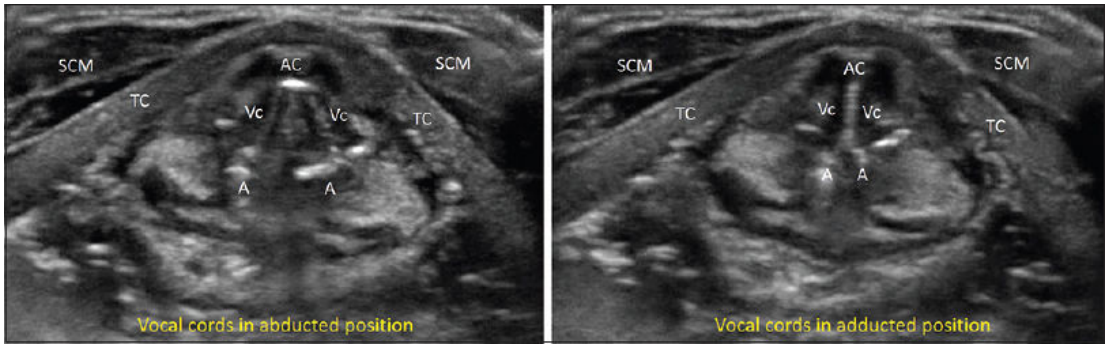


Figure 20: Vocal cord visualization at abduction and adduction.

- **Detection of position of laryngeal mask airway (LMA):** The cuff of LMA can be visualized well on transverse view. This method of confirmation is better than using fibreoptic bronchoscope (FOB) because it can be done while ventilating the patient.
- **Prediction of difficult airway:** The distance from skin to anterior surface of trachea can be measured at the level of vocal cords, isthmus of thyroid and suprasternal notch. This thickness of anterior soft tissue and neck circumference are good predictors of difficult laryngoscopy especially in obese patients. Tongue thickness and thickness of anterior neck soft tissue at hyoid bone and thyrohyoid membrane level are also useful predictors.

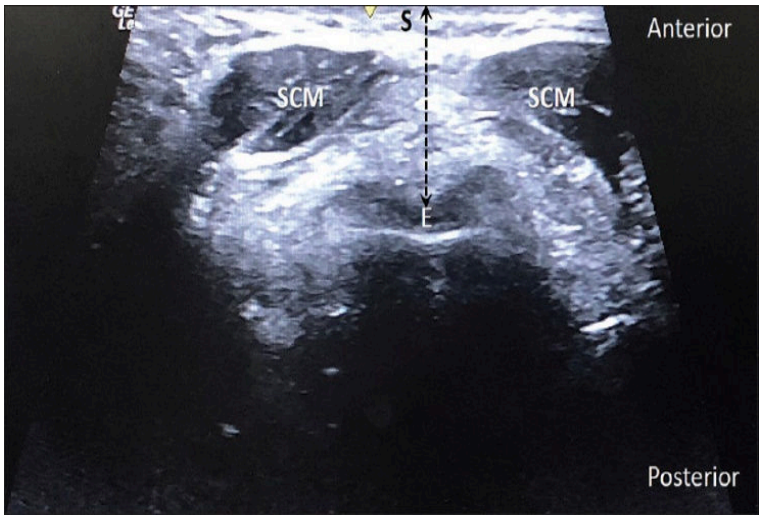


Figure 21: Distance from skin(S) to epiglottis(E): Pre epiglottic space.

❖ **Identification of cricothyroid membrane:** This is done to facilitate retrograde intubation, emergency cricothyroidotomy, percutaneous tracheotomy, assess depth from skin in obese patients during tracheostomy.

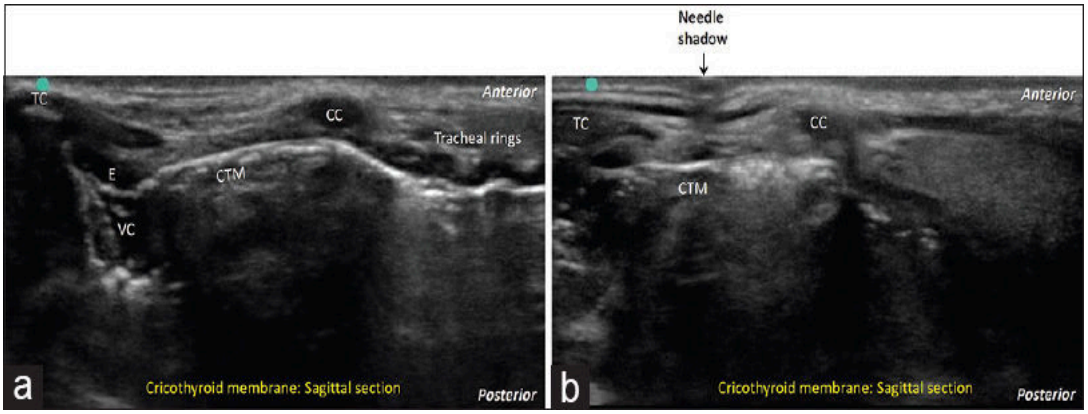


Figure 22: CTM: cricothyroid membrane; on sagittal view.

❖ **Percutaneous dilational tracheostomy:** Ultrasonography helps in performing percutaneous tracheostomy safely especially in case of neck pathologies. Safe site of puncture, minimal vessel and soft tissue injury can be ensured with ultrasound guidance.

❖ **Postextubation stridor:** Measurement of width of air column within the larynx at cricothyroid membrane level after deflating ETT cuff is useful in predicting postextubation stridor in cases of prolonged intubation and laryngeal edema following trauma.

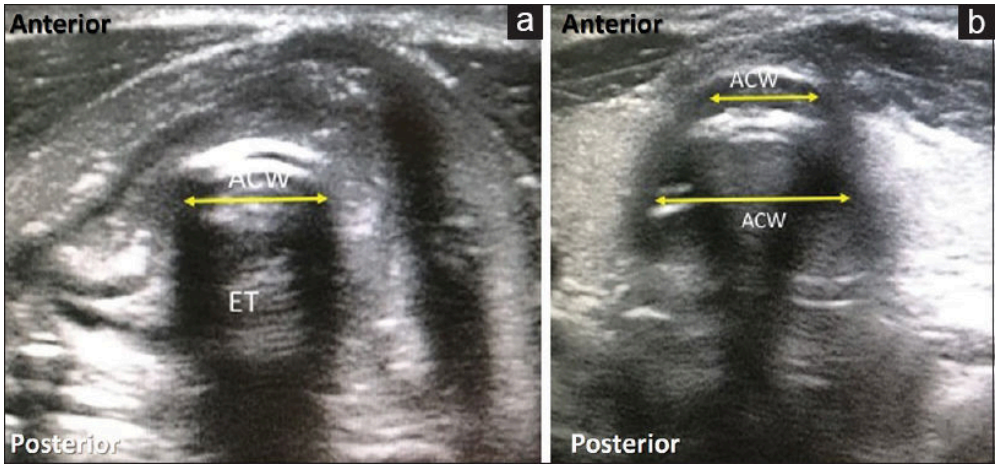


Figure 23: Trapezium shaped ACW (air column width) seen in laryngeal oedema against cylindrical ACW seen under normal conditions.

- **Tracheal wall thickness:** In males, the tracheal thickness is about 1.5 ± 0.2mm and in females it is 1.2 ± 0.2mm. Thickness increases in mucosal edema, infections, sarcoidosis, etc. Tracheal stenosis is also detected using ultrasonography for reduction in tracheal diameter or irregularity in contour. It is seen in trauma, edema, post-infection and post-intubation.
- **Identification of extent of thyroid mass:** Invasion of trachea, retrosternal extension of thyroid cancer can be detected on ultrasonography. The mass appears in continuity with the cervical thyroid.
- **Epiglottitis:** Swollen epiglottis can be detected by "P-sign" on mid-sagittal view. The anteroposterior diameter of epiglottis is increased significantly when visualized on transverse view. This is useful in pediatric population, oncology patients post radiotherapy of head and neck.
- **Maxillary sinusitis:** To visualize the sinuses and detect sinusitis. Maxillary sinus can be viewed with transducer placed transversely lateral to nose and under the eye. It is found to be useful tool of diagnosis in intubated patients.

- **Obstructive Sleep Apnea:** Polysomnography consumes time and is expensive. Ultrasound of submentum is being increasingly used which includes parameters like distance between lingual arteries, thickness of base of tongue, retropalatal space diameter, etc. The advantages being noninvasive, no radiation exposure, less time-consuming, and inexpensive.
- **Gastric Ultrasound:** It is done commonly in right lateral decubitus or spine positions. Antrum of stomach is usually viewed. A "bull's eye" is seen when stomach is empty, "starry night" when air is present in clear liquid, hypo- or anechoic area when there is clear fluid, "frosted glass" when there is solid content. It has increased use in cases of delayed gastric emptying, patients with impaired cognition or conscience, and in emergencies. Volume of clear fluids more than 1.5 ml/kg implies increased risk of aspiration. [16]

MATERIALS AND METHODS

Source of data: Patients of age 18-60 years, falling under American Society of Anaethesiologist (ASA) I and II status, posted for elective general anaesthesia with tracheal intubation with cuffed ETT at *KLE Hospital and Medical Research Centre.*

Methods:

a) **Design of study**: Prospective Observational study.
b) **Duration of study**: One year (from January 2020 to December 2020).
c) **Study population**: Female and male patients of age between 18 and 60 years posted for general anaesthesia with oral endotracheal intubation at KLE Hospital and Medical Research Centre.
d) **Size of sample**: 68
e) **Calculation of size of sample**:

The minimum size of sample is calculated using prevalence

$$n = \frac{z_\alpha{}^2 P(1-P)}{d^2}$$

***Here,* P: percentage of prevalence, d: percentage of likely difference in the prevalence.**

z_α is linked to the level of significance. For a significance of 5%, z_α = 1.96.

Ref: Prevalence of successful intubation (22/20 cm rule). Lal A, Pena E D, Sarcilla D J, Perez P P, Wong J C, Khan F A. Ideal Length of Oral Endotracheal Tube for Critically Ill Intubated Patients in an Asian

Population: Comparison to Current Western Standards. Cureus 2018 Nov 14;10(11):1-10.

With P = 58.7% and d = 20% of P = 11.74%, the sample size is 68.

f) **Place:** *KLE Hospital and Medical Research Centre, Jawaharlal Nehru Medical College, Belagavi.*

g) Selection:

Inclusion criteria:

- ASA grades I and II
- 18 to 60 years of age
- Patients scheduled for elective surgery
- Mallampatti classification 1 or 2.

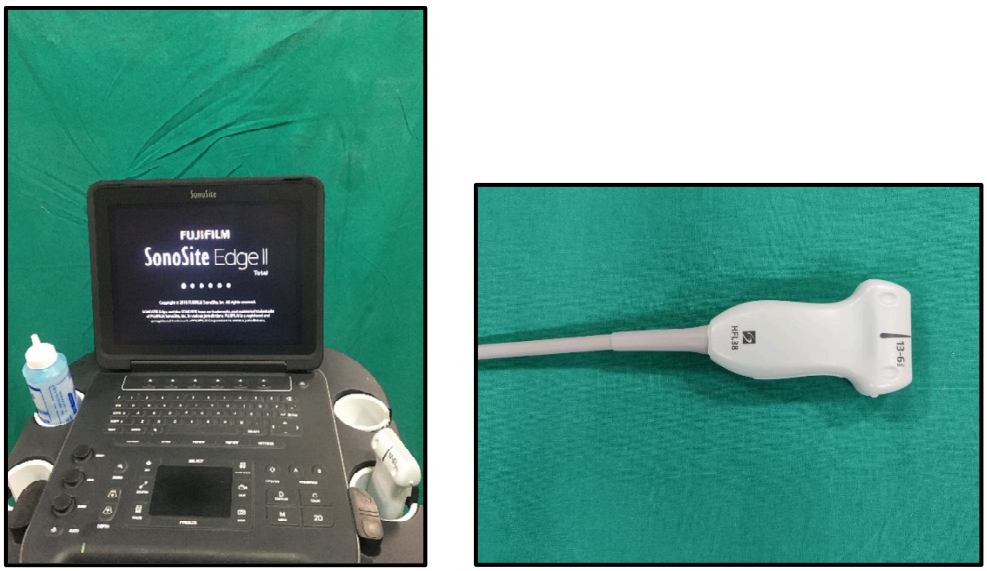
Exclusion criteria:

- Difficult airway
- History of any cervical vertebral injury
- Any abnormality in the neck.

Methodology:

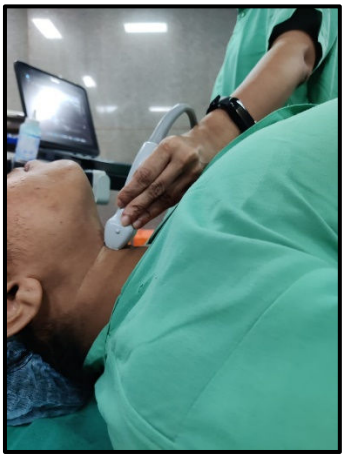
After obtaining approval from the ethics committee and informed consent from patient, a prospective observational study was carried out on patients aged 18 to 60 years, with ASA grading I or II, posted for elective general anaesthesia with tracheal intubation.

Thorough pre-operative assessment was conducted. Patient was shifted to the operation theatre and standard monitors such as pulse oximeter, electrocardiograph and non-invasive blood pressure cuff attached.



SonoSite ultrasound machine with linear transducer of 13-6 Mhz.

The patient was made to lie supine with head placed neutrally. A linear ultrasound transducer was placed in transverse orientation on the neck. The transducer was moved caudally or cranially to visualize the true cords. A line (A) drawn externally on the skin along the short axis of transducer at its midpoint represented the level of true cords.



Transverse orientation of linear probe.

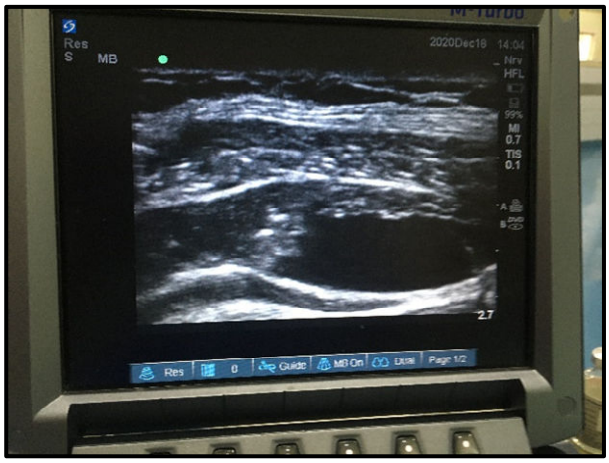
Ultrasonographic visualization of vocal cords.

On completion of induction of anaesthesia, an endotracheal tube of appropriate size was inserted by the anaesthesiologist and the cuff inflated with air. The depth of insertion was calculated using the 22/20 rule (22 cm at the level of upper incisor in males and 20 cm in females).

Transducer was then placed in a sagittal orientation on the neck cephalad to the suprasternal notch. Air was removed from the cuff which was subsequently filled with 4-5ml of normal saline. After this, two parallel hyperechogenic lines were noticed.

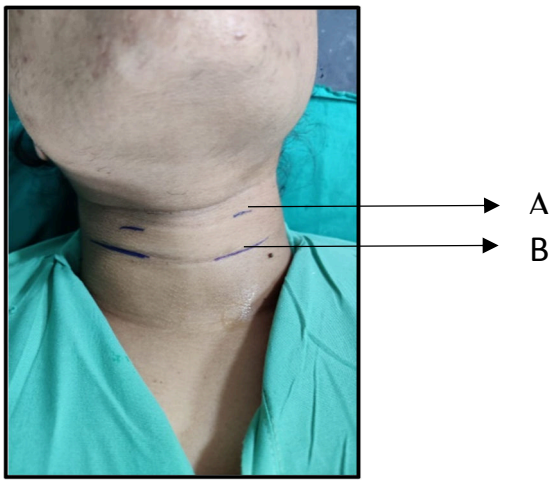
Sagittal orientation of ultrasound probe.

Normal saline (4-5 mL).



Hyperechogenic lines enhanced by filling normal saline in cuff.

The upper line constituted the cuff's anterior aspect while the lower line constituted the endotracheal tube's anterior aspect. The point where these two lines meet cranially marked the level of proximal end of cuff inflated with saline. The transducer was moved along the neck longitudinally until the proximal end of cuff appeared on the screen in its central aspect. A line (B) drawn along the long axis of the transducer at its midpoint marked the level of proximal end of cuff. The distance between A and B was measured. This constituted the vocal cord-cuff distance (VCD). Finally, the cuff was deflated and reinflated with air.



Vocal cord-cuff distance (VCD): distance between A and B.

STATISTICAL ANALYSIS

*For this observational study, the analytical plan was as follows. Mean, and standard deviation were obtained for continuous variables. For comparison, the data was divided into two groups on the basis of certain qualitative characteristics, and the continuous variables compared using "**student's unpaired t test**". Pre and post treatment measurements were compared using "**student's paired t test**". Median was used to describe discrete variables. The categorical data were expressed in terms of percentages. The linear correlation between two sets of data were measured using **Pearson's correlation**. Suitable graphs were used to represent the comparison. For all the tests, a **p** value less than 5% (0.05) was considered significant.*

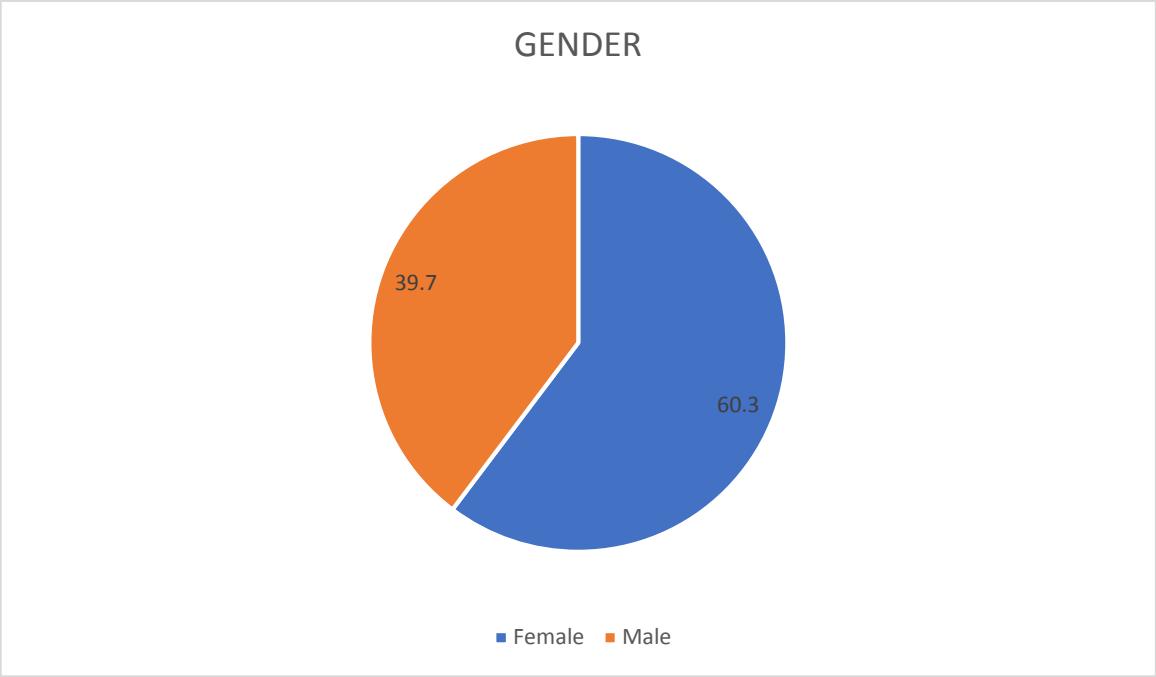
RESULTS

Among the 68 subjects included in this study, females were more in number.

TABLE No.1: SHOWING DISTRIBUTION OF STUDY SUBJECTS ACCORDING TO GENDER.

	Frequency	Percent
Female	41	60.3
Male	27	39.7
Total	68	100.0

GRAPH 1. GENDER DISTRIBUTION.

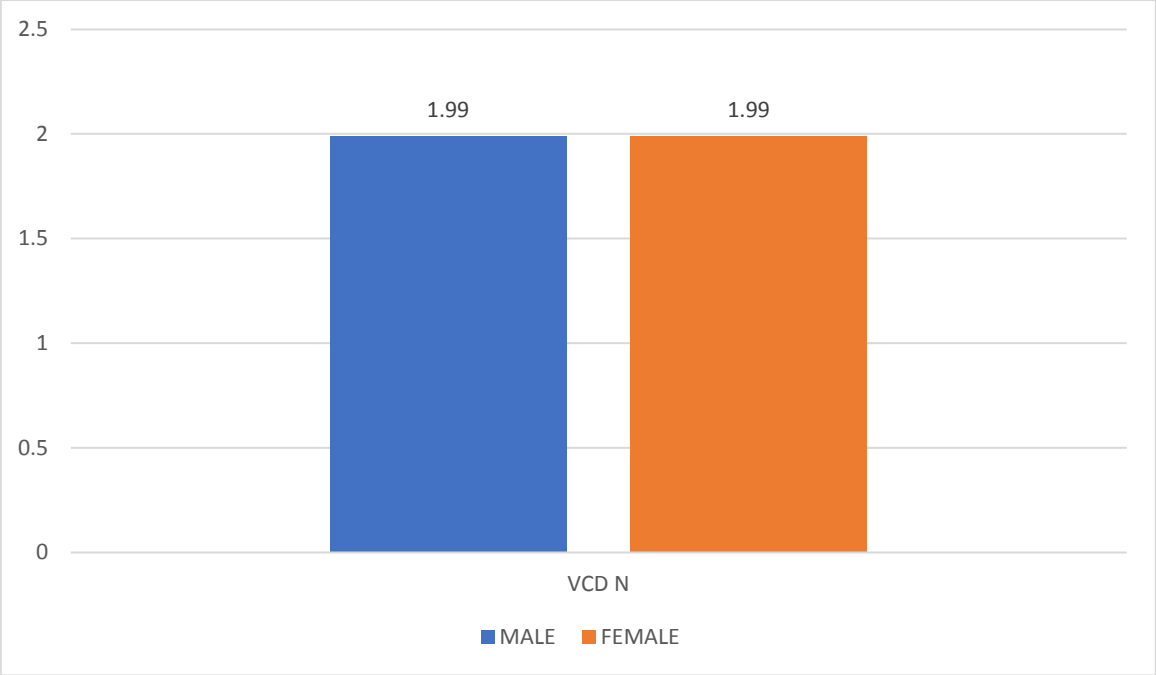


The mean values of vocal cord-cuff distance (VCD) measured in males and females were almost similar and measured about 1.99cm.

TABLE No.2: SHOWING MEAN VALUES OF VCD BETWEEN MALES AND FEMALES

	MALES MEAN ±SD	FEMALES MEAN ±SD	P VALUE
VCD (in cm)	1.99±0.32	1.99±0.30	0.739

GRAPH 2. MEAN VCD AMONG MALES AND FEMALES.



On correlating VCD with height, weight and body mass index (BMI), there was no statistical significance.

TABLE No.3: SHOWING CORRELATION BETWEEN VARIABLES OF VCD WITH HEIGHT, WEIGHT AND BMI (PEARSON CORRELATION).

		HEIGHT	WEIGHT	BMI
VCD	PEARSON CORRELATION	-.069	0.007	0.042
	SIG. (2-TAILED)	0.577	0.956	0.731
	N	68	68	68

P VALUE <0.05 IS CONSIDERED SIGNIFICANT.

INTERPRETATION

VCD is negatively correlated with HEIGHT, with Pearson's coefficient of 0.069, although it is statistically not significant with p value of 0.577.

VCD is positively correlated with WEIGHT, with Pearson's coefficient of 0.007, although it is statistically not significant with p value of 0.956.

VCD is positively correlated with BMI, with Pearson's coefficient of 0.042, although it is statistically not significant with p value of 0.731.

Among the 68 subjects, two patients had shallow intubations according to the VCD measured, and one patient had deep intubation.

TABLE No.4: SHOWING DETAILS OF THE SHALLOW AND DEEP INTUBATED PATIENTS.

SL NO	DEPTH	AGE	GENDER	HEIGHT	WEIGHT	BMI (kg/m2)	ASA	MPG	VCD (cm)
1	SHALLOW INTUBATION	30	FEMALE	160	50	19.53	1	2	1.3
		60	MALE	160	50	19.53	2	2	1.2
2	DEEP INTUBATION	42	FEMALE	158	60	24.09	2	1	2.8

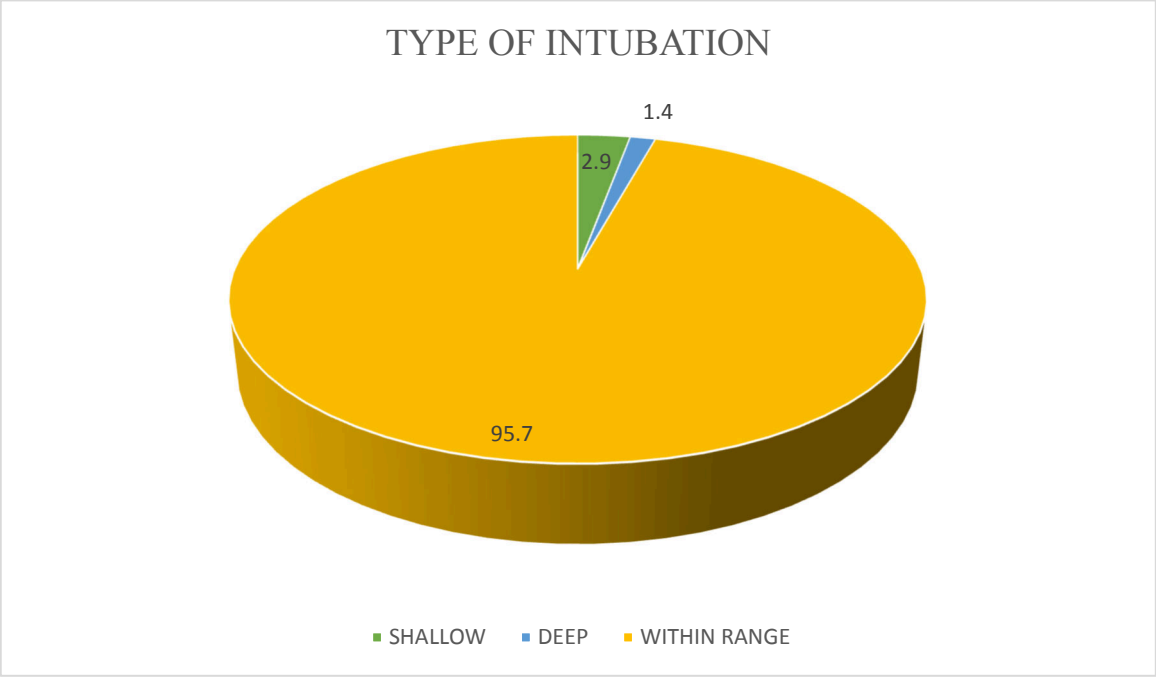
ASA: American society of anaesthesia, MPG: Mallampatti grading. Normal VCD: 1.5-2.5 cm.

Majority of patients had intubation within normal range of VCD.

TABLE No.5: SHOWING PERCENTAGE OF DEEP AND SHALLOW INTUBATIONS.

TYPE OF INTUBATION	NUMBER	PERCENTAGE
SHALLOW	2	2.9%
DEEP	1	1.4%
WITHIN RANGE	66	95.7%
TOTAL	68	100%

GRAPH 3. PERCENTAGE OF SHALLOW AND DEEP INTUBATIONS.



DISCUSSION

In our study using the 22/20 rule, out of 68 subjects, only three patients were lying out of range; two were too close to the vocal cords and one was too far from the vocal cords. The risks of shallow intubation are intraoperative laryngeal irritation and accidental extubation, postoperative nerve injury due to vocal cord impingement while that of deep intubation are carinal irritation, inadvertent intubation into the right main bronchus, hypoxemia and contralateral lung atelectiasis. These complications can be prevented by ultrasonographic measurement of the vocal cord-cuff distance and ensuring optimal placement of tracheal tube. The percentages of shallow and deep intubations in this study were found to be 2.9% and 1.4% respectively. Our study has proven by ultrasonography that the conventional method of insertion of orotracheal tube wherein it is fixed at 22cm mark at the angle of mouth in males and 20cm mark in females ensures optimal depth of the tube.

Ultrasonography has emerged as a reliable method of confirmation of tube placement. It has shown to be better than the standard auscultation method for ensuring adequate depth. It also has a high accuracy in determining optimal placement of tube, which can also be repositioned under ultrasound guidance if there is a malposition. [1]

Raphael and Conard for the first-time used ultrasound to visualize the cuff of tracheal tube by filling it with normal saline. They also stated that ultrasonography was easier, real-time, and carried no risk of irradiation and thus useful in pregnant women and critically ill patients. [9]

From previous studies, it has been well established that 23/21 rule (tube is secured at 23cm mark at angle of mouth in males and 21cm mark in females) does not apply well in Indian population.

While in western countries, optimal length has been found to be 23cm in males and 21cm in females, Amos Lal et al. suggested that in southeast Asian population the tube be fixed at least 1cm lesser to ensure safe depth.[6] Manu Varshney et al conducted an observational study in Indian population which proved fixing tube at 23cm in males and 21cm in females would lead to carinal stimulation or intubation into right main bronchus. [10] Shashi Kumari et al. compared intubation using guide marks on the endotracheal tube versus using the 23/21 rule and concluded that coinciding the black guide mark with the level of cords ensured correct placement compared to 23/21 rule. [12]

Our study is the first to validate 22/20 rule which involves fixing the tracheal tube at 22cm mark at the angle of mouth in males and 20 cm mark in females based on vocal cord-cuff distance measured using ultrasonography.

Limitations

The number of incorrect depths of intubation was small so we may have required a larger sample size. Also, since MPG 3 and 4 grades were excluded from the study, it further restricted the sample size.

Since this was purely an observational study, the tube was not repositioned if the vocal cord-cuff distance lied out of range.

Our conventional method could have been compared with the method of using intubation guide marks to see if 22/20 rule is more reliable.

This study has not compared ultrasonography with other methods of confirmation of tracheal tube depth such as fiberoptic bronchoscopy to prove the utilization and reliability of ultrasonography.

The extent of deep intubation could not be ascertained in our study since the airway distance measured here was from vocal cords to proximal end of cuff.

CONCLUSION

Fixing the orotracheal tube at 22cm mark in males and 20cm mark in females ensures adequate depth of insertion as confirmed by measurement of distance of proximal end of saline inflated cuff from the vocal cords using ultrasonography with lesser likelihood of shallow or deep intubation. Hence, 22/20 rule is a reliable method of depth of insertion of orotracheal tube.

SUMMARY

Our study titled “Assessment of conventional method of endotracheal tube insertion depth using ultrasonography in Indian Adults: A One-year prospective observational study” was conducted on 68 patients aged between 18 and 60 years in KLE hospital, Belagavi. After obtaining ethical clearance and patient consent, patients were intubated using conventional method with a depth of 22cm in males and 20cm in females. Using ultrasonography, the distance from vocal cords and proximal end of saline inflated cuff was measured. The normal range of this distance was considered as 1.5-2.5cm. In our study, two patients had a vocal cord-cuff distance less than 1.5cm and one patient had more than 2.5cm. The mean vocal cord-cuff distance was about 1.99cm in both males and females. Our study validates the conventional method of depth of insertion of endotracheal tube, thus concluding that it is safe to fix the tube at 22cm in males and 20cm in females with lesser occurrence of shallow or deep intubation.

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ANNEXURE I – ETHICAL CLEARANCE LETTER

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 220 **Date: 24/12/2019**

To,
BA0119013
PG student in Anaesthesiology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ASSESSMENT OF CONVENTIONAL METHOD OF ENDOTRACHEAL TUBE INSERTION DEPTH USING ULTRASONOGRAPHY IN INDIAN ADULTS: A ONE YEAR PROSPECTIVE OBSERVATIONAL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Anita Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE II – CONSENT FORM

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr./Mrs._____ we are requesting you to enroll your ward in study titled **"ASSESSMENT OF CONVENTIONAL METHOD OF ENDOTRACHEAL TUBE INSERTION DEPTH USING ULTRASONOGRAPHY IN INDIAN ADULTS: A ONE-YEAR PROSPECTIVE OBSERVATIONAL STUDY"**

conducted by Post-Graduate in M.D. Anaesthesiology Department of Anaesthesiology, J.N. Medical College, Belagavi under KLE University, Belagavi.

Respected Sir/Madam We request you allow your ward to participate in our study as he/she is eligible for participating in the study. During the study you will be asked some questions regarding the present complaints that your ward is having.

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.

Purpose of the study:

The purpose of research is to determine the depth of insertion of endotracheal tube by measuring the distance between endotracheal tube cuff and vocal cords using ultrasonography in Indian adults.

Procedure involved:

If you agree to enroll in my study, I will ask you present, past and family history. Then you will be clinically examined in detail. Ultrasonographic examination will be done once before the surgery and the findings will be noted. You will then be taken up for the proposed surgery and routine anaesthesia will be given. After intubation, ultrasonographic examination will be done again and findings will be noted.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll your ward in this study. Your decision will not change present or future health care services offered to you or your ward at K.L.E. S Hospital & MRC

Alternatives: Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality: The only people to know that you are a research subject is you and the 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 Department of Anaesthesiology, KLES Hospital and MRC.

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 Department of Anaesthesiology, KLES Hospital and MRC, Belagavi KLES Hospital and MRC, Belagavi.

If you have any queries about your rights as a study subject, you may call Department of Paediatrics and Chairman, Institutional Ethical Committee for Human Subjects Research, at J.N. Medical College, Belagavi.

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

"ASSESSMENT OF CONVENTIONAL METHOD OF ENDOTRACHEAL TUBE INSERTION DEPTH USING ULTRASONOGRAPHY IN INDIAN ADULTS: A ONE-YEAR PROSPECTIVE OBSERVATIONAL STUDY"

I, Mr./Mrs. _____ voluntarily agree for the participation of my ward as a subject of study. By signing this consent form, I am not giving up any of my legal rights, I may withdraw my ward from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Guardian Name: _____

Signature or the Left Thumb Print

of Guardian: _____

Date:

Witness Name: _____ Signature: _____

Investigators Name: _____ Signature: _____

Date: Place : _____

ANNEXURE III – PROFORMA

"ASSESSMENT OF CONVENTIONAL METHOD OF ENDOTRACHEAL TUBE INSERTION DEPTH USING ULTRASONOGRAPHY IN INDIAN ADULTS: A ONE-YEAR PROSPECTIVE OBSERVATIONAL STUDY"

Patient's Name: Age: IP No.:

Gender: F / M Weight:

Height: Date:

Address: Occupation:

Pre examination evaluation

Past History: H/O Cervical vertebral injury – Yes / No

General physical examination

Weight (Kg): Temperature (^{0}F): Pallor:

Cyanosis: Pedal edema: Clubbing:

PR: BP: RR:

Systemic examination:

RS : CNS :

CVS : GIT :

Airway Assessment: Mouth opening:

Teeth:

Jaw movement:

Mallampatti grading:

Preoperative physical status: ASA Grade I / II

Diagnosis:

Nature of Surgery:

Nature of Anaesthesia:

OBSERVATIONS: Patient demographic

Gender	
Age	
Height(cm)	
Weight (kg)	
BMI	

VCD (cm)	

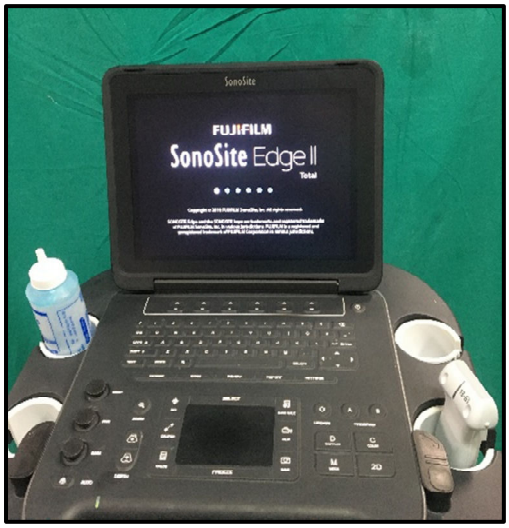
Variables are represented as mean±SD(range) or median (range).BMI, body mass index; VCD, vocal cords-cuff distance.

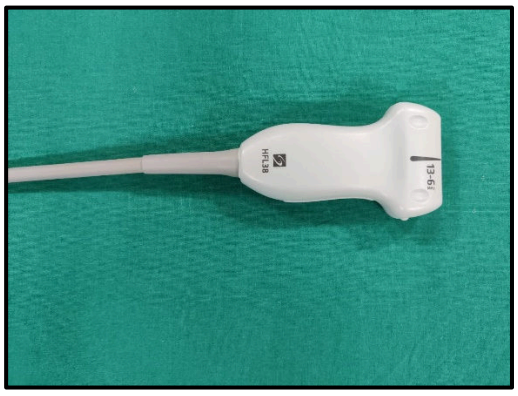
SIGNATURE OF THE ANESTHESIOLOGIST - _____

SIGNATURE OF THE GUIDE - _____

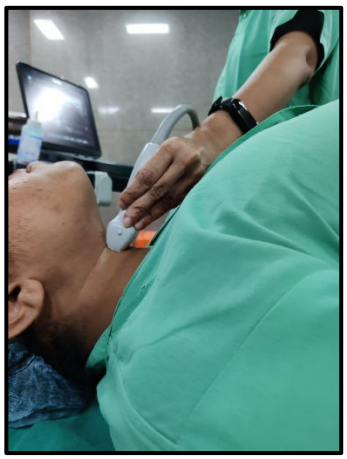
SIGNATURE OF THE PRINCIPAL INVESTIGATOR - _____

ANNEXURE – IV- PHOTOGRAPHS





Photograph 1: *SonoSite ultrasound machine with linear transducer of 13-6 Mhz.*



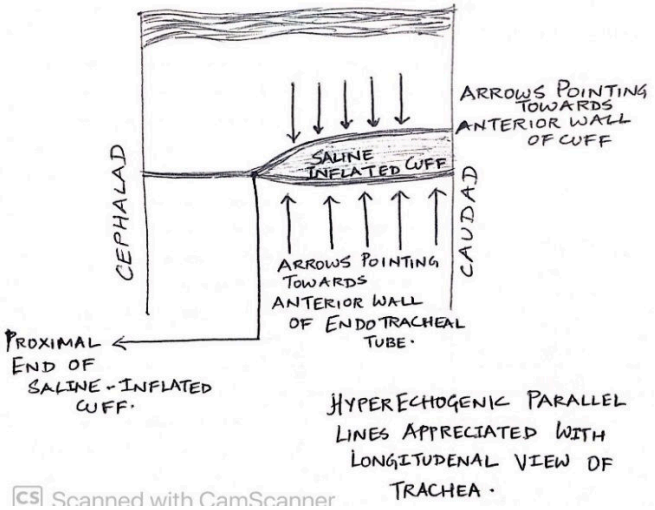
Photograph 2: *Transverse orientation of linear probe.*

Photograph 3: Ultrasonographic visualization of vocal cords.

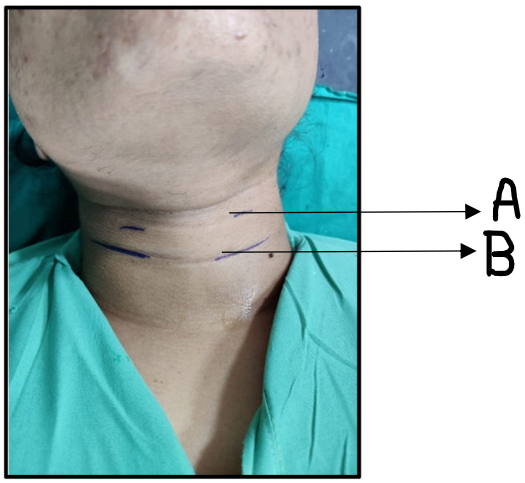
Photograph 4: Sagittal orientation of ultrasound probe.

Photograph 5: Normal saline 4-5ml filled in cuff syringe.

Photograph 6: Hyperechogenic lines enhanced by filling normal saline in cuff.



Photograph 7: Diagram of ultrasonographic view of the hyperechogenic lines.



Photograph 8: Vocal cord-cuff distance: distance between A and B.

ANNEXURE – V - KEY TO MASTERCHART

ASA	**-**	**American society of Anaesthesiologist**
BMI	**-**	**Body Mass Index**
Cm	**-**	**Centimeter**
Kg	**-**	**Kilogram**
MPG	**-**	**Mallampati Grade**
VCD	**-**	**Vocal cord-cuff distance**

ANNEXURE – VI – MASTERCHART

S.No.	IP No.	Age	Gender	Height	Weight	BMI(kg/m2)	ASA	MPG	VCD(cm)
1	996912	30	Female	158	64	25.7	I	2	2.5
2	997826	32	Female	156	58	23.86	I	2	1.5
3	1007651	20	Male	163	55	20.75	I	2	2.3
4	1012401	60	Male	163	57	21.75	II	2	2.4
5	1015506	30	Male	158	52	20.88	I	1	2.3
6	1014291	60	Male	175	76	24.83	II	2	2.5
7	1015426	52	Female	160	50	19.53	II	2	1.5
8	1015146	23	Female	155	50	20.8	I	2	2
9	1015673	19	Male	162	54	20.61	I	2	2.5
10	1015894	34	Female	160	55	21.48	I	1	2.4
11	1016155	35	Female	155	54	22.5	I	2	2.2
12	1016165	19	Female	156	42	17.28	II	2	2.3
13	1015981	31	Male	167	72	25.89	I	2	1.7
14	1015986	60	Male	165	68	25	I	2	1.5
15	1016525	18	Female	155	55	22.91	I	2	1.7
16	1016989	38	Female	154	48	20.25	I	2	1.7
17	1017454	28	Male	165	78	28.67	I	2	2.2
18	1017928	50	Male	175	74	24.18	I	2	1.8
19	1018201	39	Female	153	58	24.78	II	2	2.1
20	1019690	60	Female	158	55	22.08	II	2	1.5
21	1019776	25	Male	160	58	22.65	I	2	2.3
22	1019483	34	Female	152	75	32.46	I	2	1.8
23	1020575	45	Male	168	85	30.14	II	2	1.5
24	1021987	19	Male	165	65	23.89	I	2	2.2
25	1015543	59	Female	155	68	28.3	II	2	1.8
26	1023264	40	Female	158	45	18.07	I	2	2
27	1023330	30	Female	154	60	25.31	II	1	1.7
28	1026403	47	Female	160	50	19.53	I	1	2.1
29	1026658	38	Female	165	60	22.05	I	2	2.2
30	1026876	60	Female	170	85	29.4	I	2	2.2
31	1026967	29	Male	165	45	16.54	I	2	1.8
32	1026886	53	Male	168	84	29.37	II	2	2.3
33	1028874	30	Female	158	56	22.48	I	1	2
34	1029126	46	Female	155	55	22.91	I	1	2.4
35	1029128	38	Female	158	60	24.09	I	2	2.2
36	1028458	52	Female	154	52	21.9	I	2	2.4
37	1029135	24	Male	168	65	23.04	I	2	2.2
38	1029594	40	Male	172	75	25.42	I	2	2
39	1029945	60	Male	170	62	21.45	II	2	1.5
40	1029693	60	Male	180	80	24.69	II	2	1.5
41	1029923	60	Male	170	60	20.76	I	2	2

S.No.	IP No.	Age	Gender	Height	Weight	BMI(kg/m2)	ASA	MPG	VCD(cm)
42	1030158	35	Female	156	52	21.4	I	2	2
43	1030008	35	Female	160	58	22.65	I	2	1.7
44	1030346	24	Male	170	65	22.49	I	1	2.4
45	1020425	22	Female	160	55	21.48	I	2	2
46	1030080	30	Female	155	48	20	II	2	2.2
47	1030580	30	Female	155	55	22.91	II	2	2
48	1030866	42	Female	155	65	27	I	2	2.4
49	1031579	57	Female	156	50	20.57	II	2	2
50	1031513	29	Female	160	55	21.48	II	2	2
51	1031391	60	Female	160	60	23.43	I	2	1.7
52	1031274	60	Female	158	48	19.27	I	2	2
53	1031052	19	Female	160	48	18.75	I	1	2
54	1031120	24	Male	160	62	24.21	I	2	2
55	1032695	30	Female	160	50	19.53	I	2	1.3
56	1033140	58	Female	162	65	24.8	II	2	1.8
57	1033182	26	Male	168	65	23.04	I	1	2
58	1037003	38	Female	158	48	19.27	II	1	2
59	1037149	31	Male	168	50	17.73	II	2	1.6
60	103780	49	Female	160	65	25.39	II	2	2
61	1037798	60	Male	160	50	19.53	II	2	1.2
62	1037802	60	Male	162	60	22.9	I	1	1.8
63	1038001	31	Male	168	55	19.48	II	1	2
64	1038012	55	Female	156	55	22.63	I	2	2
65	1038229	42	Female	158	60	24.09	II	1	2.8
66	1038363	55	Female	156	62	25.51	II	2	1.7
67	1039554	21	Male	168	70	24.64	I	2	2
68	1039748	44	Female	160	54	21	I	2	2