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INTRODUCTION

Tracheostomy is known to be one of the oldest surgical procedures. There are references to the creation of a surgical airway in many ancient texts. Until towards the end of the nineteenth century and before the introduction of asepsis along with the development of safe anaesthetic techniques, the procedure was considered to be extremely dangerous and risk of fatality due to the procedure was high. Tracheostomy was considered as a last resort in hopeless cases and was the cause of great anxiety for the patient and surgeon alike. Chevalier Jackson established the principles of the operation at the beginning of the twentieth century and these remain in place today.

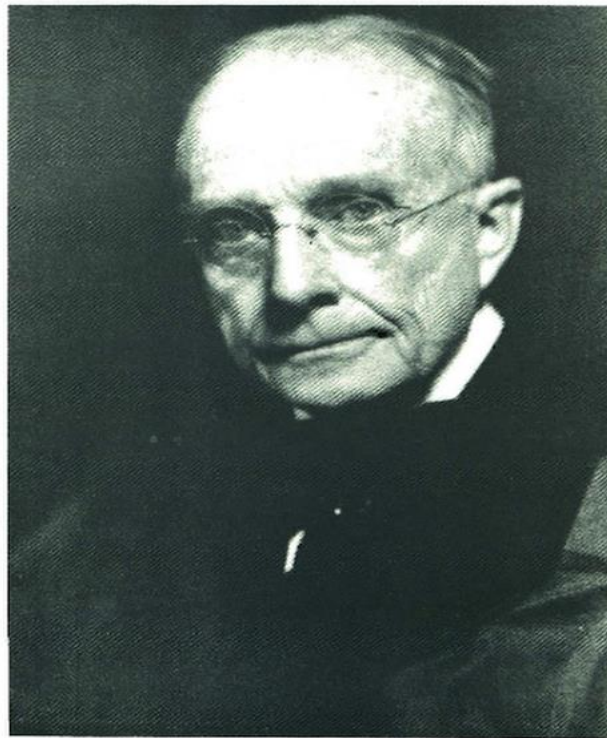


Fig. 116. Chevalier Jackson (JMC, 1886), Chairman of Laryngology (1916-24), Chairman of Bronchoesophagology (1924-30), internationally renowned for invention and improvement of instruments for removal of foreign bodies from the air and food passages.

By definition a Tracheotomy is creating a surgical opening in the trachea, whereas a Tracheostomy is creating a stoma at the skin surface of the neck that leads into the tracheal lumen.

Prolonged need for mechanical ventilation is one of the commonest reasons for elective temporary tracheostomy being performed in Intensive care unit patients.

In Intensive care units (ICU) , tracheostomy is usually indicated for critically ill patients who require prolonged mechanical ventilation, for whom in order to facilitate the removal from the ventilator machine through a weaning process. It has many beneficial effects, such as improved pulmonary mechanics, reduced laryngeal or tracheal nociceptive stimuli, shorter requirement of sedatives and analgesic medications, easier oral hygiene and nutrition and improved communication. When extended positive pressure ventilation is required, a tracheostomy is the safest method of helping ventilation. A tracheostomy tube is easier to secure than an orotracheal or nasotracheal tube and the reduced dead space helps in early weaning off the ventilatory support.

In case of prolonged intubation tracheostomy is proposed as an approach to decrease the occurrence of lung injury and further unsought concerns of prolonged intubation, like ventilator associated pneumonia, tracheal stenosis and sinusitis etc.^{4,5,6}

Apart from prolonged ventilation, some other factors like neuromuscular disease, trauma, injury severity score and age etc have also been proposed.⁷

Reduced sedation, less damage to the larynx and oropharynx, less strain for breathing, and improved access to clearing off secretions from the airway are all advantages of tracheostomy over prolonged the outcome intubation. The advantages

also include a shorter duration of mechanical ventilation and as a result, a shorter hospital and ICU stay.⁸

Different techniques are in use for performing a tracheostomy, like the classical standard surgical procedure or the percutaneous method.⁹ The two main types of tracheostomy include temporary and permanent tracheostomy.

The evidence for this yet is limited and a defined path for the management of the airway in patients is not existing.¹³

Objective:

The objective of the study includes

1. To define optimum time to carry out elective tracheostomy
2. To assess the incidence, indications, timing of the procedure and the outcome of tracheostomy on patients in the intensive care units (ICU)
3. To study the effectiveness of tracheostomy in reducing the duration of mechanical ventilation and hospital stay.
4. To study the complications (early and late) associated with tracheostomy.

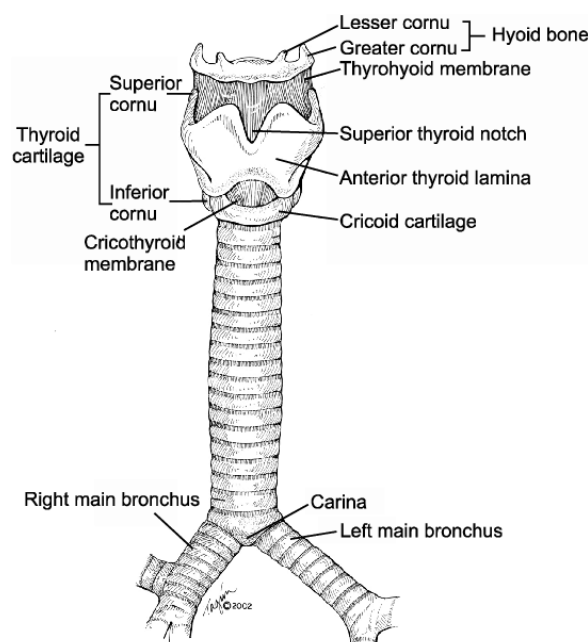


Fig: Anatomy of trachea

The trachea is a tubular cartilaginous structure in the median plane. The trachea continues from the lower part of the larynx. It extends from the cricoid cartilage's lower border to the carina. The cricoid cartilage and the lower end of the C6 vertebra forms the junction. At the location of the T4 vertebra, the trachea terminates. It splits into the left and right major bronchi.¹⁴

In an adult, the length of the trachea in the normal anatomical position ranges from 10–14cm, however it varies with age, gender and race. Above and below the suprasternal notch lies 50% of trachea. Antero posteriorly, trachea is flattened. Trachea has 16 to 20 cartilages which are C - shaped and trachealis muscle connects it posteriorly. Fibro elastic tissue connects them vertically. The trachea is easily movable and it shortens and expands on deep expiration and inspiration respectively.^{14,15}

Tracheal wall:¹⁶

It is made up of four layers,

- Mucosal
 - Lined by ciliated pseudo- stratified columnar epithelium
 - It has ample goblet cells
- Sub mucosal
 - It has loose connective tissue with glands secreting mucus
- Cartilage
- Adventitial

Relations:

Despite being a midline structure, the lower end because of aortic arch is shifted to right. The cervical part is bounded from the outer to inner aspect by skin, superficial and deep fasciae.¹⁷

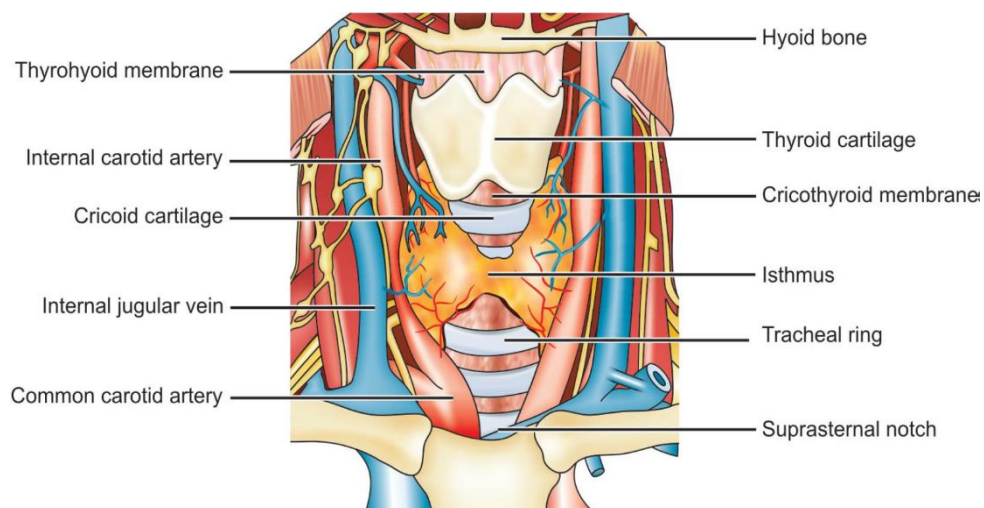


Fig: Relation of trachea

The thyroid's isthmus is positioned at level of C7 vertebra and runs parallel to 2nd, 3rd and 4th tracheal rings. Thyroid lobe inhabits the either side of the isthmus. Anastomosing vessels between the 2 superior thyroid arteries lies above the isthmus.¹⁷

Below the isthmus,

- Anterior-
 - Skin
 - Superficial fascia containing anterior jugular veins and jugular venous arch (crossing in the suprasternal space of burns)
 - Investing layer of deep cervical fascia
 - Sternothyroid and sternohyoid muscles.
 - The inferior thyroid veins,

- Remnants of the thymus
- Thyroidea ima artery.
- Posterior
 - Esophagus.

The recurrent laryngeal nerves, laterally runs in both tracheoesophageal grooves.

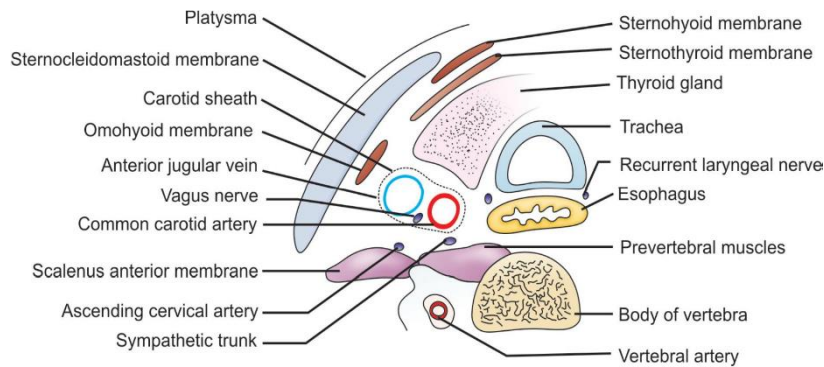


Fig: Relation of trachea with neighboring structure

Right side:

- Mediastinal pleura
- Azygos vein
- Vagus nerve

Left side:

- Aortic arch
- Left sided arteries in between pleura and trachea.

Paediatric airway anatomy

The first anatomical difference is the paediatric patient's head, which is larger than his or her body size and has significant occipital protuberance.

Positioning during tracheostomy in paediatric patients is challenging due to the bigger occiput and short neck.

The tongue is larger in newborns and children, but the mandible is smaller. The airway of an adult is more elliptical than that of a child. In children, the larynx is at a higher elevation. Cricoid cartilage is found at the C4 vertebral level at birth and at the C6 vertebral level in adults, depending on their age. The vocal cords are inclined anterior-inferior to posterior-superior to the trachea, rather than lying at right angles to it. In children, the epiglottis is more U-shaped and may lay over the laryngeal inlet. For children, the airway narrows at the level of the cricoid cartilage, but for adults, it narrows at the level of the vocal cords. In contrast to adults, the cartilaginous component of the paediatric airway is soft and compliant.

As a result, they are more likely to get obstructed when using negative pressure breathing, particularly if they already have a partial airway obstruction.

Infants have a loose mucous membrane that covers the supraglottic and subglottic regions of the airway, making them more susceptible to oedema when damaged or inflamed.

Blood supply:¹⁸

The arterial supply is from inferior thyroid arteries and bronchial arteries. The venous blood drain into inferior thyroid venous plexus which drains into left brachiocephalic veins.

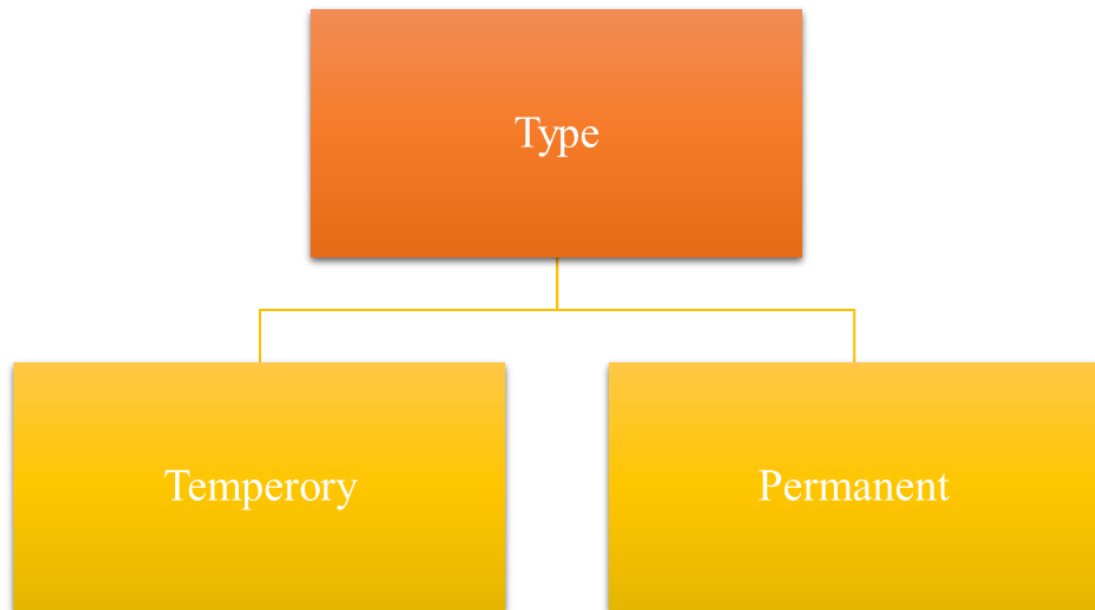
Nerve supply:¹⁸

Sensory innervation of vocal cords and trachea is by recurrent laryngeal nerve and the skin over which is from the C2 to C4 root of cervical plexus.

History of tracheostomy:¹⁹

100 AD	Antyllus performed first recognizable tracheostomy.
131 AD	Galen defined the anatomy of larynx and trachea
400 AD	Talmund described longitudinal incision can reduce bleeding
600 AD	Tracheostomy is recognized as a surgical procedure
1546 ²⁰	Antonius Musa Brasavola, an Italian physician, performed the first tracheostomy in Europe.
1718 ²¹	Lorenz Heister coined the word “tracheotomy”
1805 ²²	Viq d’Azur defined cricothyrotomy
1852	Primitive pilot tube was discovered by Bourdillat
1869	Lobster tail tube was described by Durham
1909 ²³	Surgical tracheostomy was standardized by Chevalier Jackson. He also cautioned about the complications of tracheostomy and cricothyroidotomy
1932	Prophylactic tracheostomy was advised by Wilson
1953 ²⁴	Seldinger described the guide wire needle replacement technique
1969	Trendelenburg proposed cuff in tracheostomy

Types of tracheostomy



Temporary Tracheostomy

Emergency tracheostomy is performed for patients with laryngotracheal trauma or upper aerodigestive tract cancer presenting with stridor, while elective tracheostomy is performed for patients with prolonged mechanical ventilation or surgical treatments that might contribute to upper airway obstruction.

Permanent Tracheostomy

It's also known as end tracheostomy, and it is used in surgeries such as

- Laryngo pharyngectomy
- Total laryngectomy
- Laryngeal diversion methods for relieving aspiration²⁶

Effects of tracheostomy:

1. Laryngeal bypass
2. Decreased respiratory dead space
3. Failure of nasal mucosa filtration and humidification
4. Infection risk is increased
5. Skin inflammation as the tube acts as a foreign body
6. Mucus accumulates above and below the tracheostoma sump²⁷

Indications for tracheostomy

Table 2: Indications for tracheostomy in the ICU	
Indications for tracheostomy	ICU patient groups
Facilitate prolonged assisted ventilation	Coma <ul style="list-style-type: none">• Major head injury• Cerebral bleed/infarct/lesion• Encephalitis High spinal cord injury Neuromuscular disorder <ul style="list-style-type: none">• Guillain–Barre syndrome• Critical care polyneuropathy Chronic obstructive pulmonary disease
Inability to prevent pulmonary aspiration	Posterior fossa/infratentorial lesions <ul style="list-style-type: none">• Cerebellum/brain stem• Basilar/posterior cerebral artery Cranial nerve dysfunction
Upper airway obstruction	Maxillofacial surgery or trauma Congenital malformation Facilitate upper cervical surgery Vocal cord paralysis

1. Prolonged ventilation:

When a patient is in need for prolonged positive pressure ventilation, a tracheostomy is the safest procedure. Reduced dead space makes it easy to wean from the ventilatory support. It is evaluated that ease of access and availability of adequate resources for performing a tracheostomy have decreased the endotracheal intubation duration.

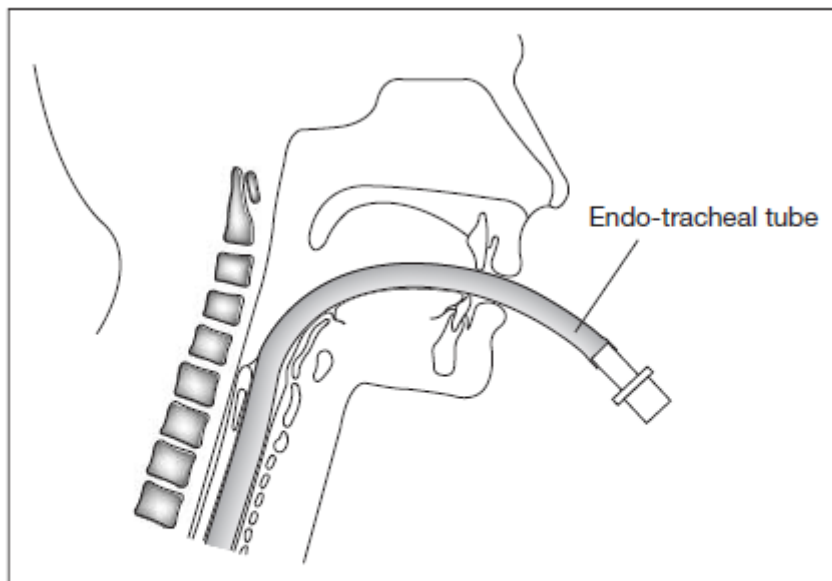


Fig. 2: A drawing of the head and neck to demonstrate the positioning of an endo-tracheal tube through the larynx.

2. Removal of secretion:

When secretion builds up in the lower airway, gas diffusion in the alveoli is reduced, leading to respiratory failure. Tracheostomy reduced the amount of dead space in the lungs, thereby reducing the amount of effort required to breathe, which helps in removal of secretion with reduced discomfort in patients.

3. Along with other procedure

For surgical procedures concerning pharynx and oral cavity, tracheostomy is done as a mandatory procedure for protection of LRT and URT from blood aspiration and post-operative oedema respectively.

4. Upper airway obstruction:

Tracheostomy is done for patients in stridor after assessing the level of obstruction, so as to provide relief.

Procedures:

Cricothyroidotomy:

In 1976, Brantigan and Grow³⁰ put forth an invasive technique of airway management called cricothyroidotomy. An opening is created in the cricothyroid membrane and a stent is placed. It is the preferred technique for achieving an emergent entry to the upper airway.

Upon identification of the cricothyroid space between cricoid cartilage and thyroid, infiltration of local anesthesia is done. Horizontal incision is made on cricothyroid membrane and is taken straight into the airway. To secure the opening, a dilating cannula is inserted. Using mayo scissor, the surgical opening is enlarged. Care should be taken to avoid injury to thyroid and cricoid cartilage. Endotracheal tube is inserted through the cricothyroidotomy to establish the ventilation. It is converted to tracheostomy upon shifting to the operation room.³¹

Cricothyroidotomy is used during an emergency situation. The reported complications of cricothyroidotomy includes

- Bleeding
- Tube displacement
- Infection
- True vocal cord damage
- Subcutaneous emphysema
- Subglottic or tracheal stenosis.

Percutaneous tracheostomy:³²

Ciaglia et al was the first to describe the percutaneous tracheostomy commonly done in western countries. The patient is positioned with sand bag behind the shoulders. The trachea is then entered by puncturing below the first tracheal ring using a needle and cannula. After confirmation of the position by using a syringe half filled with saline the needle is entirely withdrawn and insertion of guide wire through the cannula is done. After which cannula is withdrawn and graded dilators are inserted. The dilators provide a broad path that allows a typical tracheostomy tube to be properly positioned.

Tracheostomy- Surgical steps:³³

The patient should be placed in supine position and a sandbag is placed behind shoulders for extension of neck. It should be noted that both the shoulders should be at the same level, so that midline structures of neck stay in the midline during the course of the surgery.

While on local anesthesia, care should be taken for the prevention of over extension, that can restrict the airway further. Halfway between sternal notch and lower end of the cricoid cartilage, a horizontal incision is made.

Equipment for tracheostomy patient in ICU
Emergency
Tracheostomy tubes – 1
same size and 1
size smaller
Tracheal dilators
Bougie
Stitch cutters
Ambu bag PEEP valve catheter mount
Syringe
Stethoscope
Therapeutic
Humidification – heated system or heat and moisture
Exchanger
Nebuliser kit – in-line with ventilation circuit
Suction – in-line with ventilation circuit, appropriate size
Spare unfenestrated inner cannula
Cuff pressure manometer
Stoma dressing – Lyofoam
Tube ribbons or holders
Documentation – Daily observation chart: Airway
Type of tube and size
Fenestrated or unfenestrated system
Percutaneous or surgical insertion and date
Cuff pressure check 8–12 hourly – observation and manometer
Inner cannula reviewed and cleaned
Suction frequency and sputum load



Fig : Infiltration of local anaesthetic agent with adrenaline. The blanching of the skin is clearly seen.

Skin, subcutaneous tissue and strap muscles are dissected, retracted using blunt dissection. After which isthmus of thyroid is seen. Cricoid cartilage is then identified for deciding the point of entry into trachea. Bjork flap can also be used for entering into the trachea. In Bjork flap, a small portion of tracheal cartilage is pulled and sutured down to the skin. This eases the tracheostomy tube reinsertion, in case of accidental extubation. The cuff and size of tracheostomy tube needs to cross checked, so that mechanical ventilation can be given without any obstacle.

Upon entering the trachea, anesthetist or physician should withdraw the endotracheal tube upon visualizing it. The portex cuffed tracheostomy tube should be introduced once the endotracheal tube is just above the tracheotomy. The tracheostomy tube is then connected to the ventilation circuit once the cuff is inflated. The layers that have been incised are loosely closed. Using tapes and stay sutures, fix the tracheostomy tube in the right position.

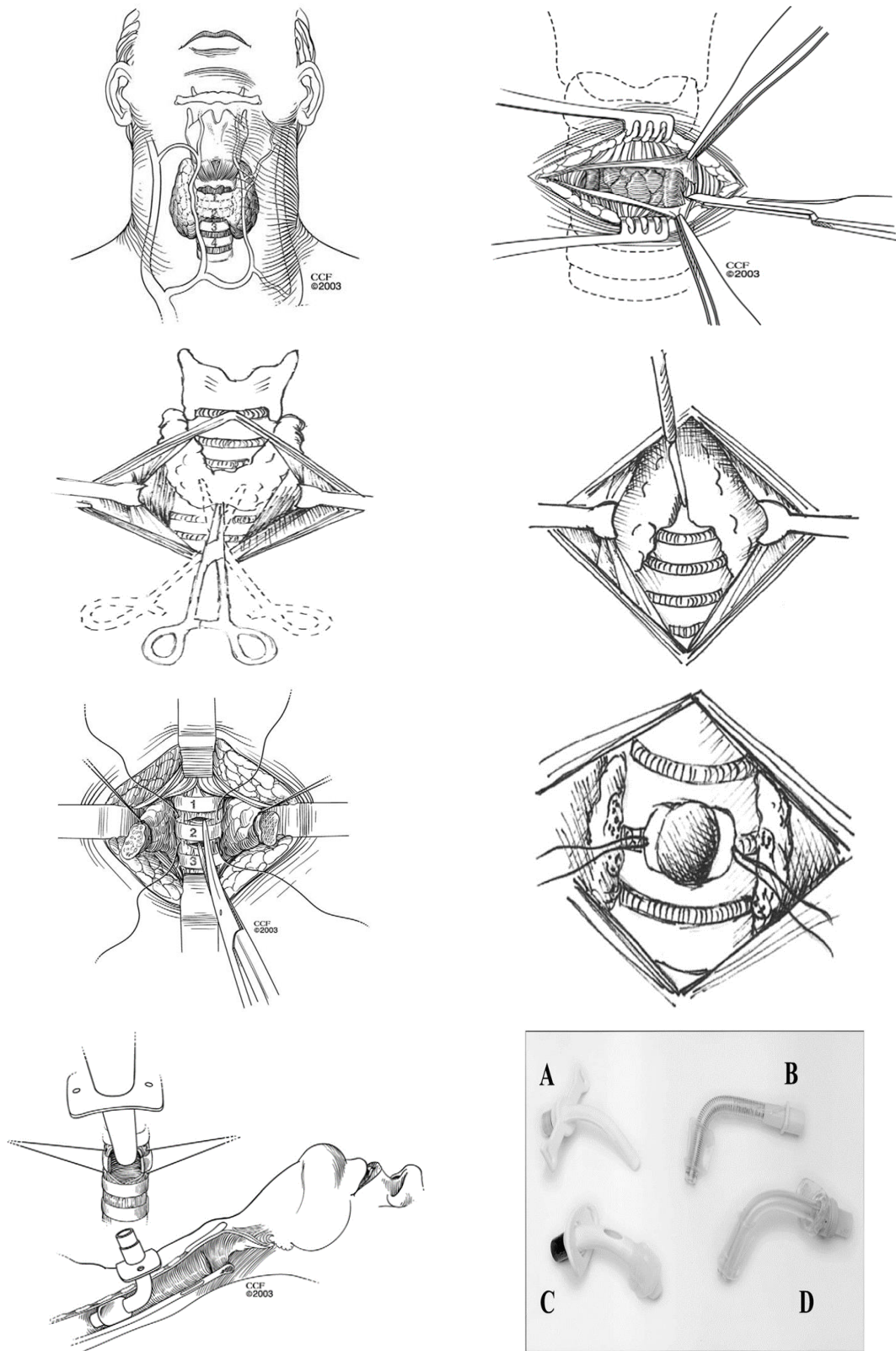


Fig: Steps of tracheostomy and available appliances

CHOICE OF THE TUBE³⁴

The postoperative demands of the patient, his or her neck anatomy, successful tracheostomy care, and the patient's comfort may all influence the tracheostomy tube selection. It is advisable to choose a tracheostomy tube that has an inner tube that can be removed and cleaned. Without obstructing the airway, the tracheostomy tube can be left in place for up to 29 days. The initial tube to be inserted should be a cuffed tracheostomy tube.

Polyvinylchloride (PVC) tubes are the most often used tubes. With or without fenestrations and cuffs, these tubes are available. A tracheostomy tube should be that of the same size as the patient's trachea.

The resistance of a very small tube can be raised, by increasing the effort of breathing on spontaneous respiration.

To prevent aspiration, increase the cuff pressure to create a tight seal around the tube. The laryngeal mucosa may be damaged as a result of this. It will be difficult to insert a large tube, which may result in inadequate leakage past the cuff during the patient's weaning process.

Minitracheostomy tubes are smaller than standard tracheostomy tubes, with a 4mm inner diameter that may be placed via the cricothyroid membrane. It can allow a suction catheter up to size 10 through it. These tubes cannot be utilised in individuals with poor airway reflexes because their diameter is too small for mechanical ventilation and they are uncuffed.

Cuff:³⁵

Cuffs offers an airtight seal, which can assist in positive pressure ventilation and prevention of aspiration of secretions . Within the cuff , the air pressure needs to be observed carefully using a cuff manometer for ensuring adequate seal. High pressure cuff with airtight seal can injure the laryngotracheal mucosa and thereby causing subglottic or tracheal stenosis. High-volume Low-pressure cuffs, with cuff pressure maintained between 15 and 25 cm H₂O can be used for prevention of these complications.

Inner tube:³⁶

Currently numerous tubes with inner tube are available commercially. The inner tube's tip is a few millimetres away from the outer tube's distal end. The main inner tube will keep the outer tube from being blocked. Meanwhile maintaining the airway patency the inner tube can be removed for cleaning.

A fenestration is formed in the tracheostomy tube at the intersection of maximal curvature as a single hole or a series of tiny holes. Fenestration of the tube via the larynx increases the amount of air accessible for phonation and improves the quality of the voice. The inner tubes with and without fenestration are available.

Fenestration:³⁷

Fenestration of tracheostomy tubes is done at the point of maximal curvature in the form of a single hole or a series of tiny holes through which air travels from the tube via the larynx, increasing the amount of air available for phonation and improving voice quality. These tubes have a fenestrated inner tube as well as non-

fenestrated tubes, allowing the patient's clinical needs to be met without compromising his or her airway.

Flexibility:

A rigid tube will not conform with the anatomy in a few patients, which in turn keeps on stroking against the lumen of trachea or may land up lying at an abnormal angle. Under such situations in order to overcome the problem, a softer flexible tube made of silicone can be utilised. Silicone made softer tubes have chances of getting kinked leading to obstruction. Hence an armoured flexible tube can be utilised. Along the shaft of the tube Metal wire are reinforced in Armoured tubes. This needs to be taken into consideration while doing an imaging study or during radiotherapy treatment.

Adjustable flange :

In case of an alteration in anatomy because of a large thyroid swelling or in order to bypass any upper airway intraluminal obstruction the tube's intratracheal length may be adjusted with an adjustable flange as the stoma depth rises.

These tubes can get easily blocked as they come without an inner tube which in turn may necessitate a tube change after 7 – 10 days. For patients with larger neck the The Uniperc TM¹ adjustable flange tracheostomy tube (Portex) has been devised which can be inserted percutaneously or surgically. Since the inner tube can be removed, cleaned, and replaced, this could stay in place for upto 29 days. It is not recommended to discharge the patient home with single-lumen tubes.

The Moores tube (Kapitex) is flexible, comes into practical use when the cuff is not needed and when a long, soft, flexible tube is needed and it possesses an

inner tube system . According to patient's needs Flexible and adjustable flange tubes can be customized.

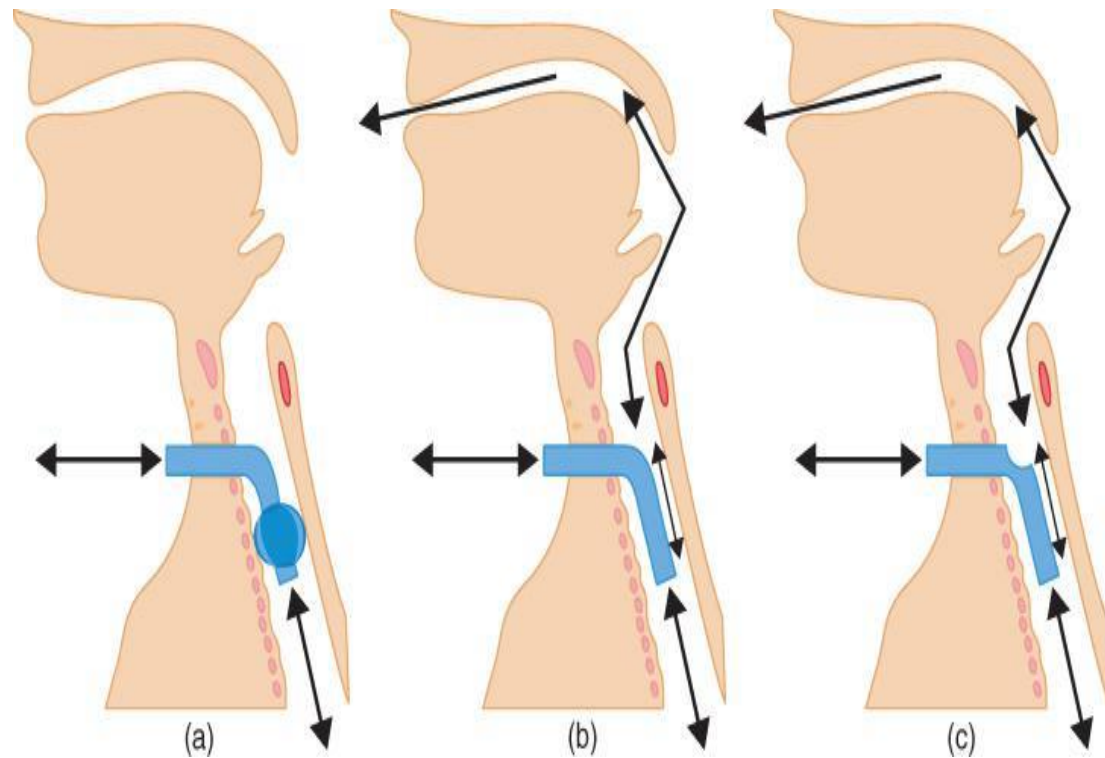


Fig: Expected airflows with cuffed tube (a), uncuffed tube (b) and (c)an uncuffed, fenestrated tube.

Choice of material for the tracheostomy tube

Selecting the most appropriate tube for each patient will include consideration of the tube material. This will contribute to both the effectiveness and comfort of the tube. The tube is required to be rigid yet flexible so as to provide adequate respiratory support, while also being a comfortable tube for the patient. It should be checked whether each patient has a known allergy to any of the products used to make the tube.

Polyvinylchloride (PVC)

This medical grade plastic is the most cost effective material for the short term tube and is used on the widest range of products. This material allows the tube to be flexible yet maintains its shape. It is also thermosensitive to adjust to body temperature. It is more prone to the retention of bacteria and is therefore disposable/single use.

Armoured tubes

These tubes have enclosed within the main shaft of the tube, a spiral or rings of stainless steel which assists in keeping the shape of the tube. This prevents kinking or compression of the tube.

E.g. Rusch, Tracheoflex

Silicone

Silicone is a soft material with the unique characteristic of reducing the adherence of bacteria and secretions to the tube by promoting the easier passage of mucus. Although single patient use it can be sterilised and therefore cost effective in long-term use.¹³

E.g. Bivona range.

Siliconised polyvinylchloride (PVC)

PVC is a thermosensitive material with sufficient rigidity for effective intubation which also can conform to the individual patient's upper respiratory tract at body temperature thereby promoting patient comfort.

E.g. Portex Blueline Ultra

Silver

Silver tubes are usually made from 92.8% silver, copper and phosphorus (trace) with silver plating.¹⁴ This mix is required to strengthen the tube although a pure silver tube would be less liable to the chemical erosion to which various alloys appear prone.¹⁴ A review of the literature includes the comment that silver tubes can fracture with prolonged use. Recommendations are that the tube should be replaced after 5 years.¹³

E.g. Negus, Chevalier Jackson and Alderhey.

Silastic

Silastic is a medical grade silicone rubber which can offer comfort and flexibility but may lack sufficient rigidity for particular clinical requirements.

E.g. Kapitex, Mooresthe

Post-operative considerations:³⁹

Proper guidelines, protocols and recommendation should be in practice for the management of tracheostomy patients. The portex tracheostomy tube need to be secured in place for at least 3 to 5 days for formation of a good tract. After 5 to 7 days from the procedure, the tube can be changed into a metallic one. Tubes must be secured with tapes with secure knot, while keeping the neck in a neutral position. If the tapes are not secured enough, accidental extubation can results. Until the risk of aspiration is present these cuffed tubes are kept inflated and in maximum number of cases the cuff can be deflated after first 12 hours.

With tracheostomy, the air is passes directly into the trachea, bypassing the humidification process and warming to decrease in nasal passage. This can result in

irritant air reaching the trachea leading to increased secretions. Because of which suctioning needs to be adequate during the post-operative period. Humidified oxygen, nebulizers and moisture exchangers can be used to reduce the chances of tube obstruction due to crust formation by the loss of moisture of the secretions. As time passes, the patient learns to cough out the secretions, thus the need for frequent suctioning is reduced. Because of pressure sensation due to inflated cuff over the upper esophagus, problems related to swallowing can occur as the movement of larynx is reduced because of the tethering effect of the tube.

A flexible nasal endoscope can usually be passed through the tube to check the lumen of the tube and the trachea if there are any uncertainties about the tube location or if the tube lumen is obstructed.

Complications:⁴⁰

Immediate:

1. Hemorrhage:

It occurs because of the injury to thyroid vein or the thyroid isthmus.

After the surgical procedure if the bleeding continues, a wound re-exploration and ligation of the bleeding vessels need to be done.

2. Air embolism:

Air embolism occurs when air is sucked into large veins. It is in a life-threatening situation.

A distorted anatomy in the hands of an inexperienced surgeon might cause damage to the contents of the carotid sheath, oesophagus, or recurrent laryngeal nerve. As they stray from the midline, the risk of injury increases.

In emphysematous individuals, the apex of the lung might extend towards the lower neck and be injured during lateral dissection. Ideal exposure can be achieved with a sufficient incision, excellent retraction, or full haemostasis, and injury to the tracheal walls or cricoid cartilage is less likely. Injury to the cricoid cartilage should be corrected during surgery. Thus if adequate haemostasis is maintained there are less chances of immediate complications.

3. Subcutaneous emphysema

This can be very dramatic, especially if the patient is receiving positive pressure ventilation.

It is most commonly caused by too tight a closure of the tracheostomy wound or an incorrectly sized tube allowing air to escape. It is important to allow the inevitable leak of some air, from the trachea, to escape to the surface of the skin.

Therefore leave the wound loosely closed with only three or four sutures and make sure the tube is the correct size for the patient.

If the situation does arise then address the above two points and cover the patient with antibiotics as cellulitis may ensue. The air will be re-absorbed spontaneously.

5. Pneumomediastinum and pneumothorax

This occurs with dissection low in the neck and damage to the pleural domes. This condition should always be suspected and a post-operative chest X-ray is performed. This condition may require an intercostal drainage tube if present.

6. *Airway fires*

This important and potentially catastrophic complication is not mentioned in any standard texts!

Fires usually arise when diathermy is used in the presence of an open airway. That is to say, when there is a source of heat, an oxygen supply and an inflammable substance available. It is well known that the gases arising from diathermied fat will burn when made hot enough or if mixed with sufficient oxygen.

It is therefore essential that a dry field be obtained prior to opening the trachea. If there is heavy bleeding from the tracheal wall after inserting the tracheostomy tube, the anaesthetist or physician should be informed so that ventilation can momentarily be suspended before using diathermy. The fumes created should be suctioned away while diathermy is in use. Bipolar diathermy is said to be safer because of less arcing, but this possibility still exists so care must be taken whatever method is used. If an airway fire should occur, empty a bowl of saline into the wound, stop ventilating the patient and use a carbon dioxide fire-extinguisher if the fire continues.

Intermediate:

1. *Accidental extubation*

It occurs when the tracheostomy tube is not secured properly by sutures to the skin.

2. *Tube displacement*

It can occur when it comes to lie in the pre tracheal space.

3. *Tube obstruction*

Soft tissues around the tube can gradually prolapse over the tracheal window and seal it. Though symptomless at first, patient can complain of dyspnea upon complete closure of the tracheal opening. A flexible scope is put through the tube's lumen to look for any tube displacement or blockage. It might be caused by crusting, granulation tissue, or improper tube tip positioning, all of which can irritate the tracheal mucosa.

4. *Cuff failure to form a seal* :

Failure to seal is detected by audible air leak into the upper respiratory tract . With positive pressure ventilation any leak is easily audible as it bubbles through the secretions in the larynx, however in the self ventilating patient use of a stethoscope positioned over the larynx is required. Once the appropriate sized tube is inserted head neck alignment and the traction forces imposed by the ventilation equipment pose significant risk to the tube position and cuff pressure. Cuff pressure is highest if the patient's head and neck are in a rotated position, less so if flexed or extended and conversely pressure is minimally affected when in neutral alignment.

Traction forces of unsupported ventilation equipment results in obvious tube torsion and potentiates tube occlusion or displacement. Thus if cuff fails to seal check alignment or support ventilation equipment, consider using a larger tube but do not over inflate the cuff. Complications of an over inflated cuff include compression of the tube, dilatation of trachea and risk of ulceration of the tracheal wall exacerbated by the presence of a nasogastric tube.

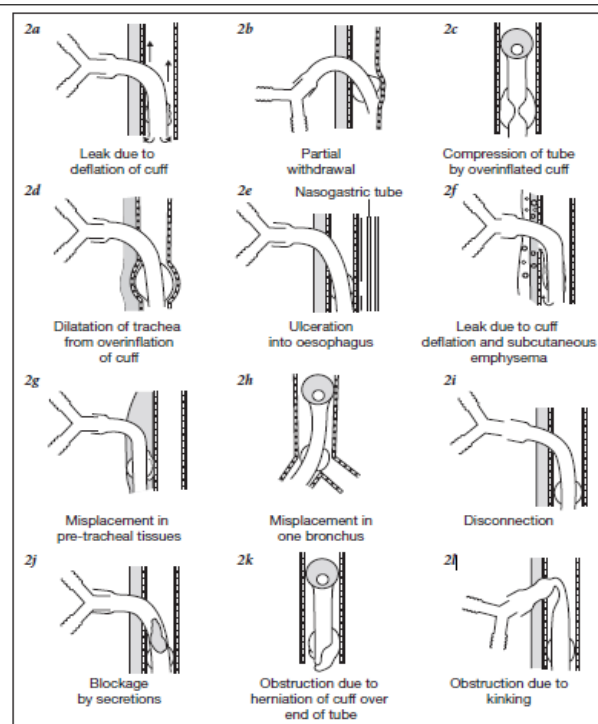


Fig. 2: Some complications of tracheostomy. From Sykes K, Young D. Principles and practice series. In: Hahn CEW, Adams AP (eds). Respiratory Support in Intensive Care, 2nd edition. London: BMJ Publishing Group, 1990.

5. Self extubation

Any patient in ICU is at potential risk to self extubate due to significant levels of anxiety, frustration and sleep deprivation. This group may experience metabolic disturbances and acute reactive depression that may include hallucinations. Those with cognitive dysfunction or in posttraumatic amnesic states post major head injury are at great risk. Information, reassurance psychological support, early speaking valve and communication aids and appropriate medication may include night sedation, anti-depressants and anti-psychotics. Extubation management follows the same guide as accidental tube displacement. Accidental Disconnection from the ventilator systems may also occur in these intubated patients.

5. Airway obstruction

This may be due to sputum or blood and is most common as a progressive encrusting of the inner surface of tracheostomy tubes. Inner cannula, appropriate

humidification, regular sputum clearance and early mobility are effective in prevention of this risk. Tubes without inner cannula should be changed regularly and at the first sign of crust formation.

Signs of tube obstruction are those of increased work of breathing, stridor and can have increased resistance to passage of suction catheter. The airway may be obstructed as a result of poor alignment of the tube within trachea. This is usually obvious from the orientation of the tube to the neck. The cuff can be herniated over the inferior pole of the tube and will require changing. Tube failure due to excessive pressure from the tracheal wall and surrounding tissues may also cause the tube to kink. This can be managed by the use of an armoured tube.

LATE COMPLICATION

1. Tracheo - oesophageal fistulae

It can happen as a result of intraoperative damage to the trachea's posterior wall or persistent rubbing of the tip against the posterior wall of the trachea, leading in mucosal irritation in the early postoperative period. Without warning signs, explosive hemorrhage can occur. To prevent aspiration, compression of the bleeding vessel need to be done and immediate wound exploration have to be done.

2. Wound infection

The tracheostomy wound always develops a low-grade infection with skin and respiratory tract organisms. This is usually a self-limiting infection and no treatment is needed. However, if there is any pressure necrosis of the skin from ill-fitting tubes and dressings then a more serious infection may occur. Sterile dressings should be changed when soiled to prevent prolonged contact of wet, contaminated dressings, with the skin. The wound should never be packed for a prolonged period to control

bleeding because this may provide a culture medium for infection, with wound breakdown and septicaemia.

Infection of the tracheal mucosa (tracheitis) may result if the trachea is allowed to dry out and this may lead to perichondritis and subsequent tracheal stenosis. Adequate humidification and correctly fitting tubes are essential to prevent this complication.

A paratracheal mediastinal abscess has been reported post-operatively but fortunately this is rare.

3. Tracheal necrosis

This is usually the result of pressure necrosis caused by an inappropriately sized tube pressing on the posterior wall of the trachea or an inappropriately high pressure within the cuff of the tube. It is therefore important to check the position of the tube and to monitor cuff pressure to prevent it.

The pressure necrosis predisposes to infection (perichondritis) and there may be erosion through the trachea into the oesophagus (tracheo-oesophageal fistula) or a vessel (tracheo-arterial fistula). The necrosis often leads to long-term tracheal stenosis.

4. Secondary haemorrhage

Minor bleeding from the skin edge may result when the vasoconstriction wears off. This is easy to control with a pressure dressing. More serious bleeding can occur from erosion of a vessel by the tube (tracheo-arterial fistula) or from an area of granulation tissue within the stoma or trachea. The granulation tissue is usually the result of local infection and or a tube, which is not fitting properly rubbing on an area

of the trachea. Therefore, make sure that the patient is getting adequate humidification, the tube is fitting properly and that there is prompt treatment of any infection.

Erosion of a tube into a large vessel is invariably fatal and occurs in 0.4% of tracheostomies.

The vessel involved is most commonly the right brachiocephalic trunk and the reasons for this have been alluded to already. Suffice to say that the tracheostomy must not be placed too low in the trachea and that the tube is the appropriate size for the patient.

5. Swallowing problems

The problem may be overcome in patients who are not at risk of aspiration by deflating the cuff during meals or by downsizing the tube. The problem usually resolves spontaneously.

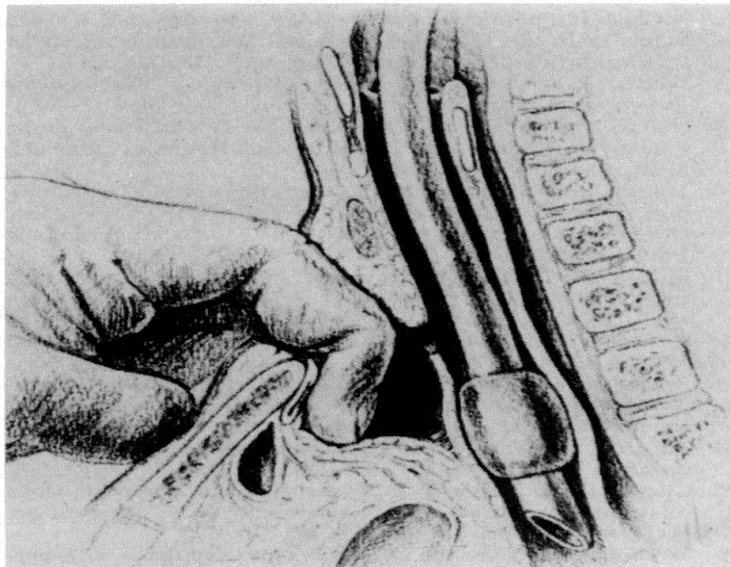


Fig: Digital compression technique

If the tracheostomy has been in place for a long time, epithelialization of the tracheostomy tract will occur. The longer the tracheostomy has been in place, the more entrenched the epithelization has become, and the more likely it is that it will continue following decannulation. Granulation tissue in the fistula can be treated with silver nitrate. Sometimes surgical closure can be needed.

Tracheal stenosis can also occur due to the cricoid cartilage or the first tracheal ring damage at the time of surgery.











6. Tracheocutaneous fistula

In long-term tracheostomies there may be complete epithelialisation of the stomal tract. These stomas will not close off spontaneously after removal of the tube. It is necessary in these patients to formally excise the stoma and to close the wound in layers, interposing the strap muscles between the skin and the trachea. This will prevent puckering of the scar, as the skin cannot adhere to the anterior tracheal wall.

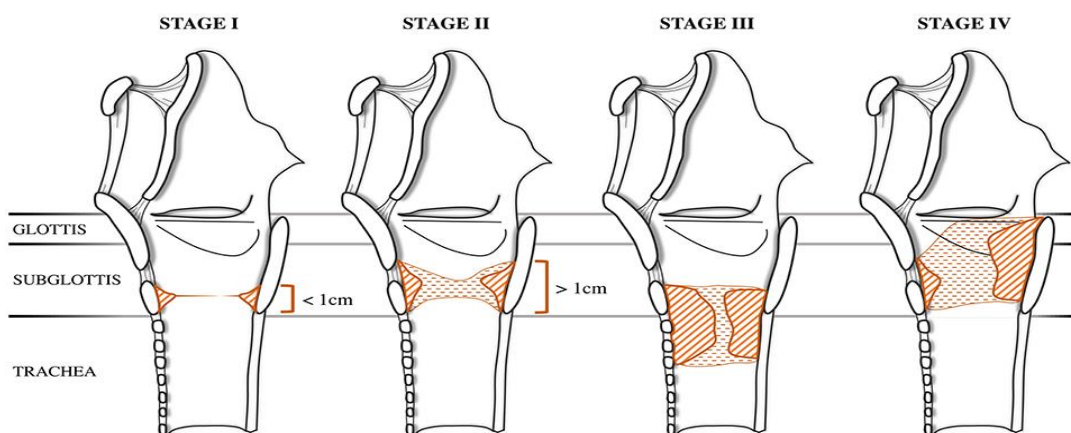
7. Laryngotracheal stenosis

Subglottic and Tracheal stenosis is almost always the result of damage to the cricoid or first tracheal ring at the time of surgery or damage to the trachea from the rubbing of a poorly positioned endotracheal or tracheostomy tube, resulting in mucosal inflammation.

- ✓ The Myer-Cotton classification was intended to describe firm and mature both pediatric and adult subglottic and/or tracheal stenosis.

Classification	From	To	Endoscopic appearance
Grade I	 No Obstruction	 50% Obstruction	
Grade II	 51%	 70%	
Grade III	 71%	 99%	
Grade IV	No detectable lumen		

✓ McCaffrey proposed a classification to describe the extension of the stenosis among the most commonly involved subsites: glottis, subglottis and trachea.



8. Tracheostomy scar

Unsightly scars are usually the result of the skin attaching to the anterior tracheal wall. This results in a puckered scar that moves on swallowing. This can be excised and the underlying strap muscles are mobilised and apposed in the midline beneath the skin, effectively preventing the skin reattaching to the tracheal wall.

9. Tracheomalacia :

Flaccidity of the supporting tracheal cartilage, enlargement of the posterior membranous wall, and diminished anterior-posterior airway calibre are all symptoms of tracheomalacia. These variables can induce tracheal collapse, especially when there is a lot of airflow, including when coughing, sobbing, or nursing. [1, 2, 3] Tracheomalacia damages the distal portion of the trachea and is linked to a number of congenital conditions, including cardiovascular problems, developmental delays, gastroesophageal reflux (GER), and tracheoesophageal fistula.

On the basis of histopathological, endoscopic, and clinical presentation, tracheomalacia can be divided into three groups:

Type I tracheal anomalies can be congenital or intrinsic, and can be linked with a tracheoesophageal fistula or esophageal atresia.

Extrinsic abnormalities or anomalies, such as a vascular ring producing excessive pressure, are symptoms of Type II.

Long-term intubation, recurrent tracheal infections, or inflammatory disorders like relapsing polychondritis can all cause Type III tracheomalacia.

Type I is assumed to be caused by immaturity of the tracheobronchial cartilage, whereas other kinds are thought to be caused by degradation of previously healthy cartilage. Degeneration can be caused by inflammatory processes, extrinsic pressures from vascular abnormalities, or neoplasms.

Table 5a: Complications of a tracheostomy tube

- Tracheal ulceration and necrosis
- Tracheal stenosis (narrowing)
- Tracheo-oesophageal fistula
- Tracheo-ominate artery fistula and haemorrhage
- Stoma ulceration and breakdown
- Overgranulation tissue
- Tracheal irritation and coughing
- Discomfort
- Cosmetic appearance

Table 5b: Complications caused by tube length

Too long

- Trauma caused by the tube tip or suction catheter catching the carina
- Collapsed lung due to unilateral ventilation caused by tracheostomy tube entering bronchi
- Patient discomfort
- Convulsive or excessive coughing due to irritation of the carina

Too short

- Tube displacement, loss of tracheostomy tract, respiratory arrest and/or death
- Tube displacement causing ventilation into pre-tracheal space leading to surgical emphysema
- Ulceration and/or erosion of the posterior tracheal wall, from poorly positioned tube within trachea
- Ineffective ventilation from a poorly positioned/angled tube within the trachea

Table 6: Complications caused by tube width

Too wide

- Tracheal ulceration
- Tracheal necrosis
- Granulation tissue caused by the shearing effect of the tube against the tracheal wall
- Discomfort
- Difficulty in swallowing
- Inability to tolerate speaking valve
- Stoma site stenosis
- Difficult tube changes
- Subcutaneous emphysema (a collection of air caused by shearing and tearing of the tracheal wall)
- Tracheoesophageal fistula caused by the tube and/or cuff pressing against the posterior wall of the trachea

Too narrow

- Inadequate ventilation
- Increased respiratory effort
- Ventilator indicates leakage via nose and mouth
- Ineffective clearance of secretions
- Increased risk of aspiration from an inadequately sized tube and cuff (while maintaining recommended cuff pressures)

Table 7: Complications from cuffs

Over inflated cuff (Fig. 7)

- Tracheal mucosa ischaemia causing ulceration and erosion
- Tracheoesophageal fistula, caused by cuff pressing the posterior tracheal wall
- Tracheoinnominate fistulae, necrosis of the tracheal mucosa and artery wall, this can lead to a potentially fatal bleed
- Laryngotracheal stenosis
- Difficulty in swallowing

Under inflated cuff

- Insufficient seal for ventilation
- Aspiration of saliva and gastric contents into the tracheo-bronchial tree

Decannulation

Initially, the cuffed tube needs to be replaced by an uncuffed tube. Then downsizing of the tube needed to be done. For the first 24 hours, the tube must be closed during the day and then unblocked at night. If the patient can tolerate it, the tube should be blocked again for another 24 hours. After removal of tracheostomy tube an airtight dressing should to be applied for the tracheostomy stoma closure. The patients have to be instructed that while coughing and talking, they need to support the tracheostomy stoma site once strapping of the tracheostomy stoma is completed.

BENEFITS OF A TRACHEOSTOMY

Patients with tracheostomies tend to have fewer days of mechanical ventilation because of the improvements in the respiratory physiology, as alluded to earlier. The airway is more secure than with an ET tube, particularly if the patient is transported to other parts of the hospital (e.g.X-ray or theatres) or not sedated and therefore able to move about in bed. Less sedation is required as the tube is more comfortable than an ET tube.

The patients may also be able to swallow, so may be started on oral feeding sooner and mouth care is easier compared with an ET tube. The most significant benefit from a patient's point of view is that they can communicate more easily, either by articulating or mouthing words or by using a speaking valve and/or fenestrated tube.

PROTECTION OF THE TRACHEOBRONCHIAL TREE FROM ASPIRATION

In chronic conditions where laryngeal or pharyngeal incompetence will allow aspiration and inhalation of saliva or gastric contents, a tracheostomy should be performed. A cuffed tube will prevent aspiration of fluids and the tube allows easy access to the trachea and the bronchi for suction.

Examples include:

Neurological diseases [polyneuritis (e.g. Guillain–Barre syndrome), motor neurone disease, bulbar poliomyelitis, multiple sclerosis, myasthenia gravis, tetanus, brain-stem stroke and bulbar palsy].

Coma (in any situation where the Glasgow Coma Scale score is less than 8, the patient is at risk of aspiration as the protective reflexes are lost.

That includes head injury, overdose, poisoning, stroke, and brain tumour.

Trauma (severe facial fractures, may result in the aspiration of blood from the upper airways).

WEANING THE TRACHEOSTOMY PATIENT ON ICU

Tracheostomy patients in an ICU form a heterogeneous group so that implementing a uniform weaning strategy is not practical. Within this group there will be those who wean off mechanical ventilation in days, 1–2 weeks or longer than a month. All patients may have particular needs, but the philosophy of a weaning program are incorporating periods of work and rest and mean while avoiding fatigue can be successfully applied to all.

Weaning should begin as soon as the patient's condition has been stabilised. Early reintroduction of spontaneous respiratory effort has been shown to be beneficial. By encouraging early respiratory muscle activity the disuse atrophy associated with immobility and mechanical ventilation can be lessened. There is a plethora of suggested predictors for successful weaning however on review none are recommended for formal use. It is recommended that a daily trial of spontaneous breathing and patients on prolonged ventilation been shown to benefit from use of Yang's Rapid Shallow Breathing Index. This allowed patients to accelerate the weaning steps thus decreasing ventilator days.

REVIEW OF LITERATURE

Lanza et al. in (1990)⁵³ retrospectively reviewed head injury patients to examine the predictive value of the GCS for tracheostomy in these patients. Of 47 patients divided according to their GCS rating, 34 had a $GCS \leq 7$ and 13 had $GCS > 7$. They found that the likelihood of tracheostomy is significantly greater in patients with $GCS \leq 7$.

Rodriquez et al. in (1990)⁴⁴ studied 106 mechanically ventilated trauma patients in a prospective randomized controlled study. They randomized 51 patients to early tracheostomy (within 7 days of intubation) and 55 patients to late tracheostomy (> 7 days). They were able to demonstrate a significant decrease in the duration of mechanical ventilation, and ICU and length of hospital stay in patients randomized to early tracheostomy.

D'Amelio et al.in (1994)⁵⁸ studied 43 trauma patients retrospectively, tracheostomy was done in 31 patients. Patients who had tracheostomy done within the first 7 days of intubation had lower mechanical ventilation duration as well as ICU and hospital length of stay.

Koh et al. in (1997)⁵⁹ conducted a retrospective study on 49 patients, 20 of which were victims of trauma, who required admission to the neurosurgical ICU. In this study, the reintubation rate was 22% despite meeting weaning criteria. Among the predictors of failed extubation were low Glasgow Coma Scale (GCS) and excessive tracheal secretions

Sugerman et al in (1997)⁶⁰ found no difference between ET and LT group in the incidence of pneumonia.

Chia-Lin Hsu and his colleagues⁵⁵ did a retrospective study of 163 patient in July 1998 –June 2001. 93 male and 70 female; mean age 70 years, range 19–104 years; The indications for intubation in the 163 patients were categorised into: pulmonary (n = 107), infectious (n = 18), neurological (n = 28) and circulatory (n = 10) disease.. The mean number of days of intubation was 18.5 ± 10.9 days (range 1–62 days). The most common early complication of tracheostomy was bleeding (moderate amount in 11 [6.7%] and minor bleeding in 46 [28.2%]), followed by subcutaneous emphysema (3 [1.8%]; In two this occurred along with bleeding and in one it occurred with air leakage) and obstruction (3 [1.8%]). The most common late complication was bleeding in 4 patients [2.5%]), followed by air leakage (3 [1.8%]) and tracheal stenosis in 2 patients [1.2%]). The patients who underwent early tracheostomy also had shorter post-tracheostomy ICU stays (10.8 versus 14.2 days) and weaning periods (19.0 versus 44.3 days, $P < 0.001$). The early tracheostomy patient group had a greater rate of successful weaning (56.4% versus 30.2%, $P = 0.002$) and lower ICU mortality (14.5% versus 28.3%, $P = 0.05$), but there were no differences between early and late tracheostomy groups in terms of hospital mortality.

Bouderka et al in (2004)⁶² studied reduced duration of mechanical ventilation, shorten ICU stay and hospital stay .Also studied no difference in pneumonia between ET and continued intubation(58vs61%),delay in pneumonia occurrence(6.7 ± 1.8 vs 9.2 ± 2.3) and faster recovery from ventilator dependence (6 ± 4.7 vs 11.7 ± 6.7).

Rumbak MJ et al (2004),⁴³ did a prospective randomized study with 120 patients with the objective to assess the outcome in patients with early tracheostomy when compared to late tracheostomy. The results showed that the hospital mortality was 31.7% and 61.7% among the early and late group respectively. He found reduced

time of mechanical ventilation in early tracheostomy group (<48 hrs) 7.6 ± 4.0 vs 17.4 ± 5.3 days (late tracheostomy group >48 hours). He also found reduced length of stay in intensive care units for patients in early tracheostomy group (4.8 ± 1.4 versus 16.2 ± 3.8 days)

Moller et al in (2005)⁶⁴ compared ICU patients before and after tracheostomy. He found reduced ICU length of stay (16.7 ± 1.0 vs 26 ± 1.3 days) as well as shortened hospital stay (22.8 ± 1.2 vs 33.4 ± 1.7 days) in patients whom had early tracheostomy. He also found decrease in VAP after ET (27 vs 72%).

H Flaatten et al (2006)⁶³ did a study on 461 patients retrospectively and found reduced median number of days on ventilator after ET (4.7 vs 14.7 days). he also studied decreased length of stay in ICU patients after early tracheostomy (≤ 7 days) compared with LT (6.8 vs 12.7 days).

Bickenbach J et al (2011),⁴⁵ conducted a retrospective analysis among ICU patients with the aim to determine the effect of timing of tracheostomy in weaning. The results showed that ICU mortality was higher among the late group than the early and intermediate group. (40.7% vs 24.8%). The incidence of pneumonia and length of ICU stay was significantly lower among the early group. However, there was no significant difference in the duration of weaning among the groups.

Zheng Y et al (2012),⁴⁶ conducted a prospective randomized trial among 119 adult patients with the objective to aim to determine the effect of timing of tracheostomy on clinical outcome. The results showed that the ICU discharge (67.2% and 47.5%) and successful weaning (74.1% vs 55.7%) was significantly higher in early tracheostomy group than in late tracheostomy group. Pneumonia was seen among 29.3% and 49.2% of the early and late tracheostomy group respectively. However, there was no significant difference in the mortality between the groups.

Young D et al (2013),⁴⁷ performed an open randomized trial among critically ill patients with the aim to compare the early versus late tracheostomy in the outcome of the patients. The median critical care unit length of stay among the survivors was 13.0 and 13.1 days in early and late group respectively. Complication was seen among 5.5% and 7.8% in the early and late group respectively.

Liang Meng et al in (2016)⁶⁸ did a systematic review and meta analysis and found that in a total 2040 patients,1018 had early tracheostomy while 1022 had late tracheostomy. They inferred from their meta-analysis and suggested that Early Tracheostomy might be able to reduce the duration of sedation but did not significantly alter the mortality, incidence of VAP, duration of MV and length of ICU stay.

Jeon YT et al (2014)⁴⁸, did a study among 125 patients with the aim to assess the effect of tracheostomy timing in the clinical outcome of the patients. The results showed that the total Mechanical Ventilation duration (21.5 vs 11.4) and length of stay in ICU (31.1 vs 19.9) were significantly higher in late tracheostomy than the early tracheostomy group. The frequency of ventilator associated pneumonia was lower among the early than the late group. (23 vs 44). However, there was no significant difference among the in-hospital mortality among the study participants.

Mohamed KA et al (2015),⁴⁹ conducted a study among 40 patients with the objective to compare the early and late tracheostomy in terms of outcome among the ICU patients. The results showed that there were significant differences in mechanical ventilation duration which was lower in early than the late tracheostomy group. (32.2 versus 20.6). The mean ICU length of stay was 21 vs 40.14 among the early and late tracheostomy group respectively. The mean hospital stay was also lesser among the early than the late group (34.6 vs 55.6).

Whited et al (1984)⁶⁹ found a 12% incidence of laryngeal stenosis in patients with tracheal intubation for 11 days or longer, a 5% incidence between 6-10 days of intubation, and a 2% incidence with less than 6 days intubation.

AIMS AND OBJECTIVES

1. To define optimum time to carry out an elective tracheostomy
2. To assess the incidence, indications, timing of the procedure and the outcome of tracheostomy on patients in the intensive care units (ICU)
3. To study the effectiveness of tracheostomy in reducing the duration of mechanical ventilation and hospital stay.
4. To study the complications (early and late) associated with tracheostomy.

MATERIAL :

Case details of patients admitted in Intensive care units undergoing tracheostomy and Medical records department in RGGGH AND MMC from January 2020 to October 2021.

DATA COLLECTION :

The study was started after obtaining Institutional ethical approval. Clinical, Hospital medical records , Radiological investigations and Videolaryngoscopic evaluation were analysed. The purpose and procedure of the study was explained to the enrolled participants/caretakers in their local language. Patient information sheet and informed written consent was obtained from the participants/care takers before initiating the study .

The following data will be taken for the study purpose and evaluated.

Name

Age and sex

IP No:

Date of Admission and Diagnosis

Patient's Glasgow Coma Scale

Day of intubation

Event of reintubation

Day of tracheostomy After Intubation

Reason for tracheostomy

Immediate and intermediate complications

Day of Weaning after tracheostomy

Day of Metallic Tube Change

Day of transfer out from ICU

Day of strapping

Day of discharge after tracheostomy

Follow up visit

Late complications

These patients were assessed on various parameters like GCS, Reason for tracheostomy, total duration of mechanical ventilation, length of ICU stay, time taken for decannulation, complications associated with tracheostomy, total duration of hospital stay and follow visit assessment with video laryngoscopy findings by one month and six months after discharge.

METHODOLOGY

It is a prospective observational study of patients admitted in intensive care unit patients requiring mechanical ventilation and undergoing tracheostomy in the intensive care units. After getting approval from the ethical committee, this study was conducted. It was carried out in our tertiary care hospital affiliated to a teaching Institute. The period of the study is from January 2020 to October 2021.

The total number of patients included in our study are 100, above 12 years age of patients of which includes male , female and transgenders.

Case details of patients undergoing tracheostomy in Intensive care units with a thorough history taking, detailed clinical examination and with appropriate Radiological investigations and Videolaryngoscopic evaluation for a Prospective observational study methodology was done.

These patients were divided into patients on mechanical ventilation with endotracheal requiring tracheostomy depending on the timing of tracheostomy ,Early tracheostomy if done within one week (≤ 7 days)after intubation and Late tracheostomy group if done after one week (≤ 7 days) post intubation. Late tracheostomy group is further sub divided based on the day of trachesotomy i.e., (8 to 14 days) , (15 to 21 days) and (> 21 days) after endotracheal intubation.

GLASGOW COMA SCALE : When the Glasgow Coma Scale (GCS) goes below 8, these patients were intubated. The Glasgow coma scale was created to determine the severity of neurological damage.. It consists of the following components of assessment namely movement, speech and eye opening. The severity of the brain damage is divided into three categories: severe (GCS less than 8), moderate (9-12), and mild (GCS more than or equal to 13). This clinical assessment must be carried out immediately to determine whether the patient can maintain airway on his own or not and also to determine the prognosis of the patient.

TABLE 38-2		
Glasgow Coma Scale		
BEHAVIOR	RESPONSE	SCORE
Eye opening response	Spontaneously	4
	To speech	3
	To pain	2
	No response	1
Best verbal response	Oriented to time, place, and person	5
	Confused	4
	Inappropriate words	3
	Incomprehensible sounds	2
	No response	1
Best motor response	Obeys commands	6
	Moves to localized pain	5
	Flexion withdrawal from pain	4
	Abnormal flexion (decorticate)	3
	Abnormal extension (decerebrate)	2
	No response	1
Total score:	<i>Best response</i>	15
	<i>Comatose client</i>	8 or less
	<i>Totally unresponsive</i>	3

Image courtesy : glasgow-coma-scale-gcs-first-aiders

On the third day, a spontaneous breathing trial (SBT) was undertaken. SBT refers to a person's ability to breathe spontaneously (i.e., extubation readiness). This is decided by the patient's breathing pattern, gas exchange rate, haemodynamic stability, and level of comfort.. If he or she can endure SBT for 30-120 minutes, he or she is regarded clinically fit. A Failed SBT is determined by the following parameters

<p>Signs of intolerance to spontaneous breathing (weaning failure)</p> <p>$\text{PaO}_2 < 50\text{-}60 \text{ mmHg}$ and $\text{FiO}_2 > 0.5$</p> <p>$\text{SaO}_2 < 88\text{-}90\%$ and $\text{FiO}_2 > 0.5$</p> <p>$\text{PaCO}_2 > 50 \text{ mmHg}$ or increased by more than 8 mmHg</p> <p>$\text{pH} < 7.32$ or reduced by more than 0.07</p> <p>$\text{RR} > 35 \text{ breaths/min}$ or increased by more than 50%</p> <p>$\text{HR} > 140 \text{ bpm}$ or increased by more than 20%</p> <p>$\text{SBP} > 180 \text{ mmHg}$ or $< 90 \text{ mmHg}$</p> <p>Uncontrollable psychomotor agitation</p> <p>Reduced level of consciousness</p> <p>Excessive sweating and cyanosis</p> <p>Evidence of increased respiratory muscle effort</p>

In the case of a poor cough, increased upper airway resistance, respiratory weakness masked by pressure support, emergence of any new pathology, copious secretions and poor airway reflexes leading to aspiration, a few patients will require reintubation. If SBT fails, intubation will be continued or a tracheostomy will be performed.

According to Griffiths and Barber et al, tracheostomy patients are split into two groups: early tracheostomy (surgery performed within one week of intubation) and late tracheostomy (surgery performed at any time after one Week of intubation).

They defined an early tracheostomy (ET) as "a tracheostomy performed within seven days of admission to the critical care unit, the start of translaryngeal intubation, and mechanical ventilation (2005)." Any time after this interval is considered late tracheostomy (LT).

Tracheostomy is performed with the patient supine position and a sand bag beneath the shoulders under local anesthesia.

The Jackson's safety triangle (triangle formed by the anterior border of the

sternocleidomastoid on either side and the lower border of the cricoid cartilage as the upper limit) is used to represent the site of local infiltration.

From the lower border of the cricoid cartilage to 2cm above the suprasternal notch, a vertical incision is created. Strap muscles are located and retracted away from the midline when the skin and subcutaneous tissue are dissected. Dissection of the investing layer of the deep cervical fascia done. Thyroid isthmus was identified and resected or retracted superiorly. The position of the trachea has been confirmed.

Then, between the second and third tracheal rings, a tracheal window is constructed.

A low-pressure, high volume Portex tracheostomy tube of appropriate size is inserted and the bulb is inflated. Hemostasis is attained completely. Wound is closed in Layers.

The airway is examined and ensured to be sufficient on both sides. Perioperative problems such as haemorrhage, abrupt desaturation, tube displacement, tube in false track, and so on are investigated.

Following are the post-procedure instructions:

1. For the first 4 hours, deflate the cuff for 5 minutes once per hour, then 5 minutes every fourth hourly for the following 24 hours, after which the cuff may be deflated if not contraindicated.

2. Proper Humidification

3. Suctioning on a frequent basis: The most crucial measures to remember when suctioning are to only do it for 30 to 60 seconds at a time. Suction catheter diameter is one-third or less than one-third of the inner diameter of an adult tracheostomy tube

inserted which not more than 15 cm. Suction pressure should be kept between 8 and 15 mmhg. The patient is weaned off the ventilator and the decannulation process begins after their overall condition has improved and they meet the following criteria. Stable arterial blood gases, a PaCO₂ of less than 60 mmHg, no respiratory distress, haemodynamic stability, the presence of a gag reflex, and the capacity to expectorate are the requirements.

Then comes the day when weaning from the ventilator after a tracheostomy is addressed. Patients are subsequently transferred from the intensive care unit to a general male or female ward, where the portex tube is replaced with a fuller's biflange d metallic tracheostomy tube. The number of days from tracheostomy to ICU discharge is then calculated, and the early tracheostomy group is compared to the late tracheostomy group.

Sphigotting is done for an entire 24 hours after a metallic tube replacement, but if the patient exhibits respiratory distress, it should be withdrawn.

Tracheostomy stoma strapping is done when sphigotting has been tolerated well. The day of decannulation is noted within two weeks, the stoma wound will heal.

From the day of admission until the day of discharge, the average number of days spent in the hospital is determined and compared across two study groups.

The patients' immediate outcomes are analysed, and they are subjected to Videolaryngoscopy (VDL) within one month following discharge, with the procedure repeated after six months Thus the final outcome of patients are assessed at the end of 6 months.

STUDY PLACE : Upgraded Institute of Otorhinolaryngology,
Rajiv Gandhi Government General Hospital,
Chennai – 600003.

STUDY DESIGN : Prospective Observational study

STUDY PERIOD : JANUARY 2020 to October 2021

ETHICAL CLEARANCE : Obtained.

CONFLICT OF INTEREST : NIL

FINANCIAL SUPPORT : NIL

INCLUSION CRITERIA :

Totally 100 patients admitted in Intensive care units (ICU) satisfying the inclusion criteria was included in the study.

1. Patients above 12 years of age
2. All sexes (male , female and Transgender)
3. Patients on admission in ICU and on mechanical ventilation undergoing tracheostomy.
4. Patients on follow up after weaning from ventilator and Post tracheostomy status.

EXCLUSION CRITERIA :

1. Patients of age less than 12 years , uncooperative patients
2. Patients not willing to complete treatment
3. Patients not willing for the study
4. Patients with pre existing laryngeal and tracheal trauma.
5. Patients with associated head and neck malignancies.

BENEFIT TO THE COMMUNITY :

1. Emphasize the need of early tracheostomy for a shorter period of mechanical ventilation and eventually decreased length of ICU and hospital stay.
2. Avoidance of potential life threatening complications.
3. Reduction of morbidity and mortality associated with ICU admission and mechanical ventilation.

Ethical consideration:

Institutional Ethical Committee approval was obtained before starting the study. The participants were explained that the data collected in this study will be used only for research purposes. The participants were explained about the freedom of withdrawal from the study at any time without penalty or loss of benefits. The confidentiality of the data collected from the enrolled participants was maintained in all the phases of the study. The study participants who required medical attention during the period of intervention will be given appropriate medical care.

STATISTICAL ANALYSIS:

The collected data was checked for completeness before entering into the Microsoft excel spread sheet. The validation of the data was checked at regular intervals. Data analysis was performed with an intention to treat approach using Statistical Package for Social Sciences (SPSS IBM) 21. The quantitative data was expressed in frequency and percentage. To test the statistical significance of the difference in the mean of continuous functional outcome between 2 groups, Student's t test/ Kruskal Wallis test was applied and to test the statistical significance of the difference in proportion of categorical factors between 2 groups, Chi square test was used. p value less than 0.05 was considered significant.

RESULTS

Table 1: Age distribution among the study participants

S no	Tracheostomy done (days)	Age		P value
		Mean	SD	
1	≤7 (Early)	43.51	13.94	0.359
2	8 to 14 (Late)	39.83	14.80	
3	15 to 21 (Late)	40.67	13.84	
4	>21 (Late)	29.50	0.70	

- The mean age of the study participants was 41.60 ± 14.7

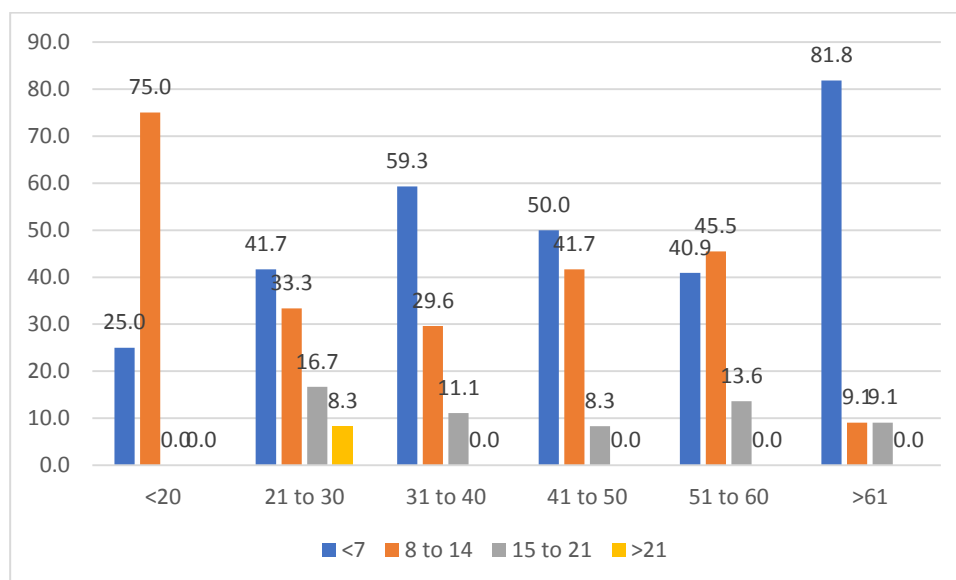


Fig: Age distribution among the study participants

Table 2: Distribution of timing of tracheostomy among the study participants

S no	Tracheostomy done (days)	Frequency	Percentage
1	≤ 7 (Early)	51	51
2	8 to 14 (Late)	35	35
3	15 to 21 (Late)	12	12
4	>21 (Late)	2	2

- 51 % of the study participants had Early tracheostomy i.e., less than or equal to 7 days of endotracheal tube intubation and 49 % had late tracheostomy anytime after the 7th day of intubation.

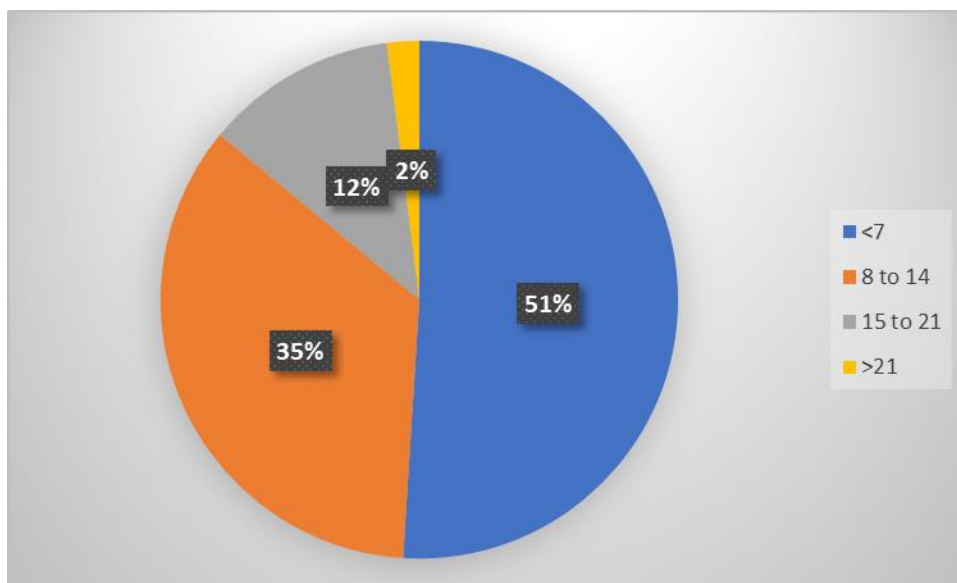


Fig: Timing of tracheostomy

Table 3: Gender distribution among the study participants

S no	Tracheostomy done (days)	Gender				P value
		Female		Male		
		N	%	N	%	
1	≤7 (Early)	14	45.2	37	53.6	0.188
2	8 to 14 (Late)	11	35.5	24	34.8	
3	15 to 21 (Late)	4	12.9	8	11.6	
4	>21 (Late)	2	6.5	0	0	

- Majority of the study participants were male participants. 69 male and 31 female participants.

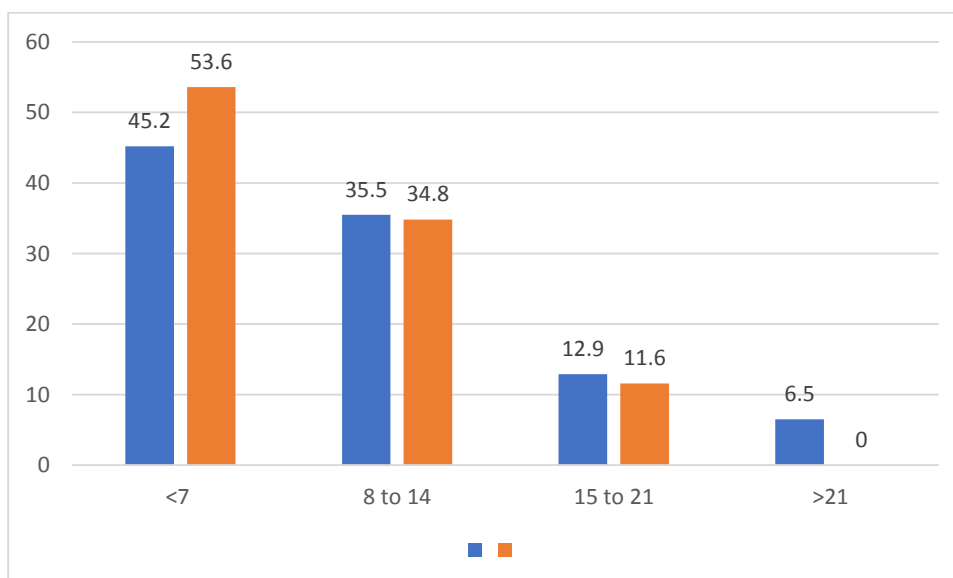


Fig: Gender distribution among the study participants

Table 4: GCS on day 1 among the study participants

S no	Tracheostomy done (days)	GCS on day 1		P value
		Mean	SD	
1	≤7 (Early)	7.12	1.25	0.126
2	8 to 14 (Late)	7.03	1.09	
3	15 to 21 (Late)	6.50	0.90	
4	>21 (Late)	8.00	0.00	

- The mean GCS on day 1 was 7.12, 7.03, 6.5 and 8.00 among those who had tracheostomy at ≤7, 8 to 14, 15-21 and >21 days respectively. The difference was statistically insignificant.

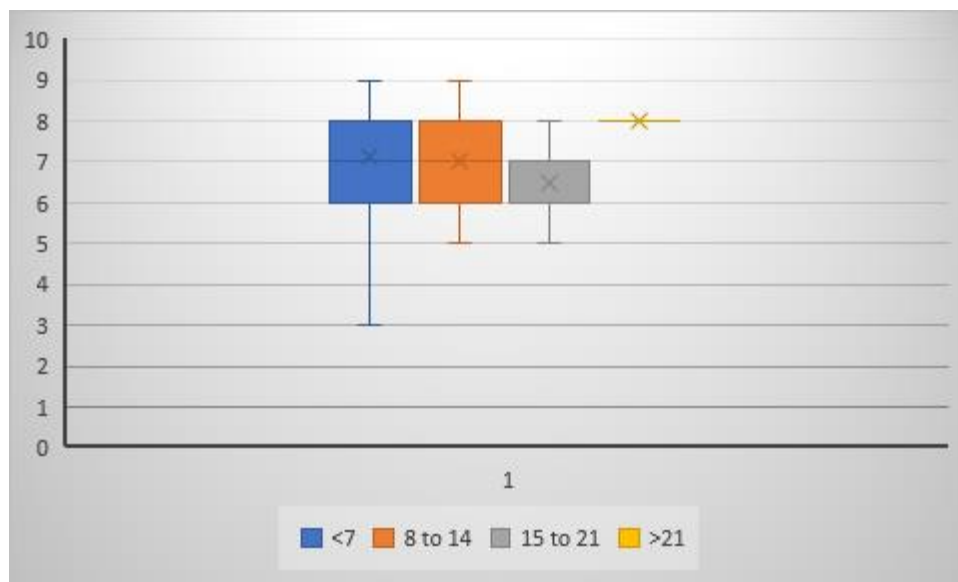


Fig: GCS on day 1 among the study participants

Table 5: GCS on day 3 among the study participants

S no	Tracheostomy done (days)	GCS on day 3		P value
		Mean	SD	
1	≤7 (Early)	6.46	1.11	0.235
2	8 to 14 (Late)	6.57	1.91	
3	15 to 21 (Late)	5.67	1.30	
4	>21 (Late)	6.5	2.12	

- The mean GCS on day 3 was 6.46, 6.57, 5.67 and 6.5 among those who had tracheostomy at ≤7, 8 to 14, 15-21 and >21 days respectively.
- The difference was statistically insignificant.

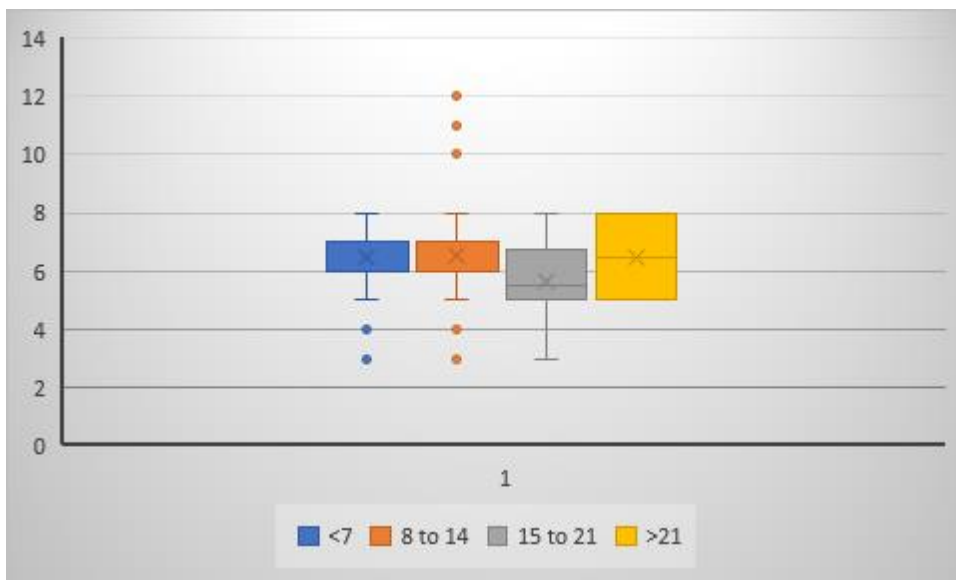


Fig: GCS on day 3 among the study participants

Table 6: Day of tracheostomy from the day of intubation among the study participants

S no	Day of tracheostomy	Day of tracheostomy		P value
		Mean	SD	
1	≤7 (Early)	5.24	1.06	<0.001
2	8 to 14 (Late)	10.03	1.85	
3	15 to 21 (Late)	16.75	1.29	
4	>21 (Late)	23	1.41	

- The mean day of tracheostomy was 5.24, 10.03, 16.75 and 23 among those who had tracheostomy at ≤7, 8 to 14, 15-21 and >21 days respectively.
- The data is statistically significant.

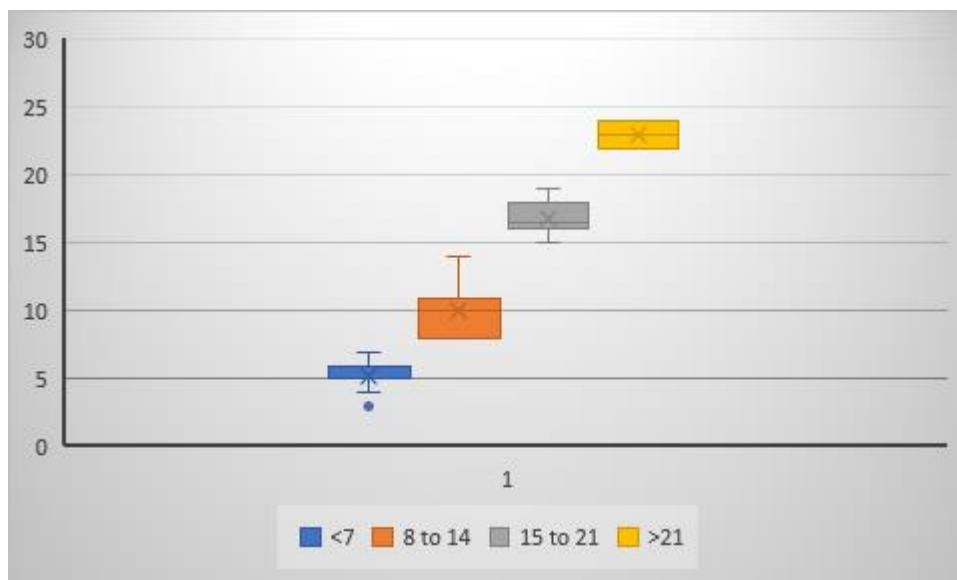


Fig: Mean timing of tracheostomy

Table 7: Diagnosis and the timing of tracheostomy among the study participants

S no	Tracheostomy done (days)	Diagnosis								P value
		Medical		Neurological		RTA		Toxicology		
		N	%	N	%	N	%	N	%	
1	≤7 (Early)	10	50	10	40	3	60	28	56	0.940
2	8 to 14 (Late)	7	35	10	40	2	40	16	32	
3	15 to 21 (Late)	3	15	4	16	0	0	5	10	
4	>21 (Late)	0	0	1	4	0	0	1	2	

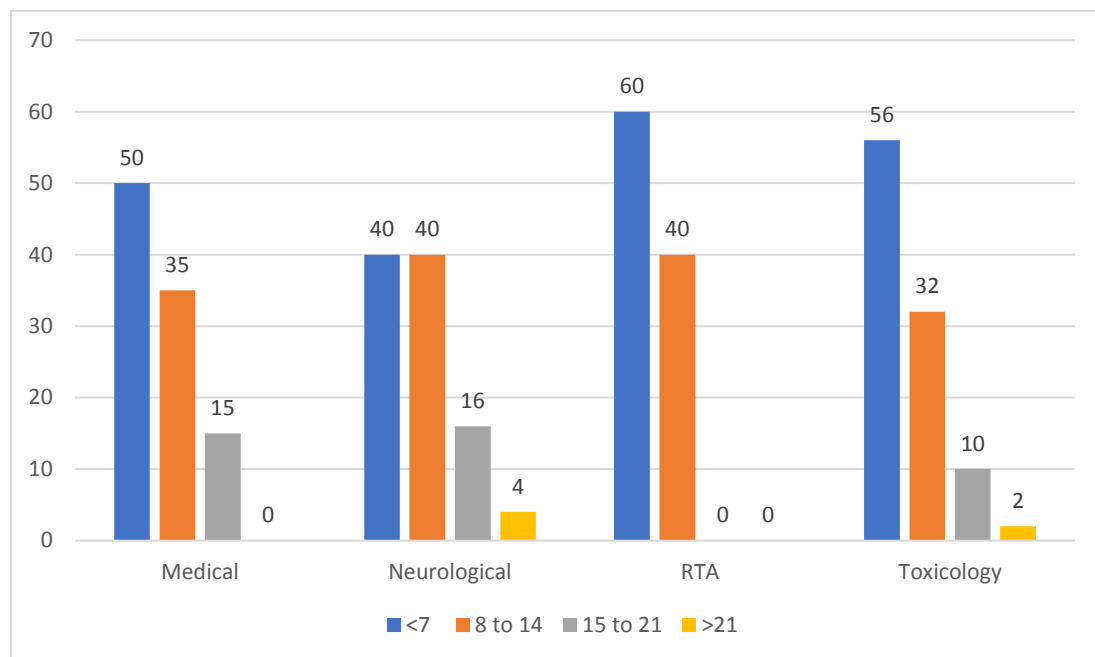


Fig: Diagnosis among the study participants

- The present study was conducted in our institute which is a tertiary care referral centre and has shown that among those participants with medical diagnosis, 50% had early tracheostomy and 35%, 15% had tracheostomy at 8 to 14 and 15-21 days respectively.
- Among those with neurological diagnosis, 40% had early tracheostomy and 40%, 16% and 4% had tracheostomy at 8 to 14, 15-21 and >21 days respectively.
- Among those with RTA 60% had early tracheostomy and 40%, had tracheostomy at 8 days.
- Among those with toxicology diagnosis, 56% had early tracheostomy and 32%, 10% and 2% had , tracheostomy done at 8 to 14, 15 to 21 and >21 days each.

Table 8: Reason for tracheostomy among the study participants

S no	Tracheostomy done (days)	Reason for tracheostomy						P value
		Respiratory failure		Prolonged ETT Mechanical Ventilation		Tracheobronchial toileting		
		N	%	N	%	N	%	
1	≤7 (Early)	20	69	17	36.8	14	58.8	<0.001
2	8 to 14 (Late)	8	27.6	24	51.1	3	12.5	
3	15 to 21 (Late)	1	3.4	4	8.5	7	29.2	
4	>21 (Late)	0	0	2	4.2	0	0	

- Among those who had tracheostomy during less than or equal to 7 days, majority 69% had respiratory failure.
- Among those who had tracheostomy on 8 to 14 days and > 21 days group , majority 51.1% and 4.2% respectively had prolonged ventilation as reason for tracheostomy.
- Among those with tracheostomy on day 15 to 21, majority had tracheobronchial toileting as the reason for tracheostomy.
- The difference was statistically significant.

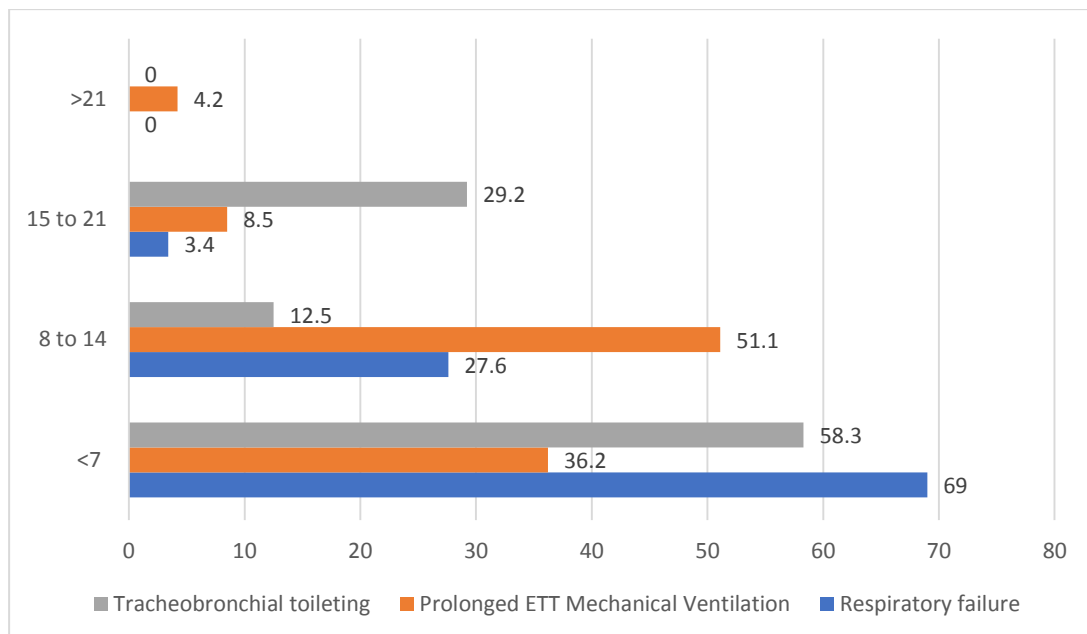


Fig: Reason for tracheostomy among the study participants

Table 9: Re-intubation among the study participants

S no	Tracheostomy done (days)	Reintubation				P value
		Yes		No		
		N	%	N	%	
1	≤7 (Early)	9	17.6	42	82.4	0.046
2	8 to 14 (Late)	19	54.3	16	45.7	
3	15 to 21 (Late)	7	58.3	5	41.7	
4	>21 (Late)	1	50	1	50	

- Reintubation was significantly higher among those who had late tracheostomy.
- The data is statistically significant.

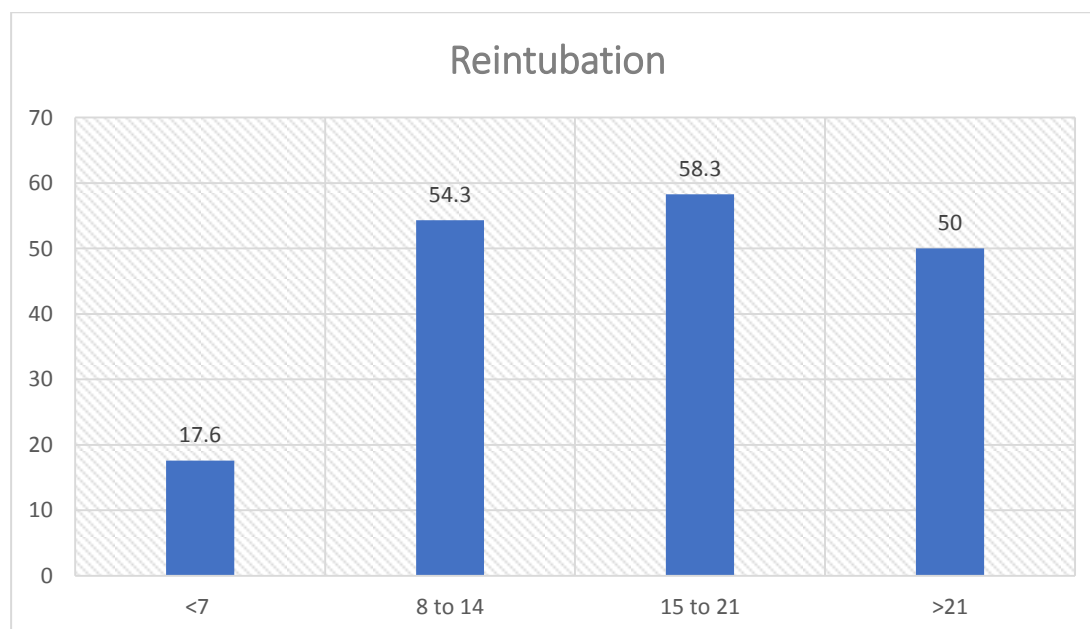


Fig: Reintubation among the study participants

Table 10: Immediate and Intermediate Complications among the study participants.

S no	Tracheostomy done (days)	Immediate and Intermediate complications								P value
		Tube displacement		Tube block		Bleeding		Stoma bleeding		
		N	%	N	%	N	%	N	%	
1	≤7 (Early)	1	33.3	0	0	1	33.3	0	0	0.218
2	8 to 14 (Late)	2	66.7	4	100	1	33.3	0	0	
3	15 to 21 (Late)	0	0	0	0	1	33.3	1	100	
4	>21 (Late)	0	0	0	0	0	0	0	0	

- In early tracheostomy group 2 patients had complications i.e., 1 patient had tracheostomy tube displacement and 1 patient had intraoperative bleeding.
- In late tracheostomy group 9 patients had complications, i.e., in 8 to 14 days group 2 patients had tracheostomy tube displacement, 4 patients had tracheostomy tube block and 1 patient had intra operative bleeding. In the 15 to 21 days group 1 patient had intraoperative bleeding and 1 patient had tracheostomy stomal bleeding.
- Immediate and intermediate complication was higher among those with late tracheostomy.

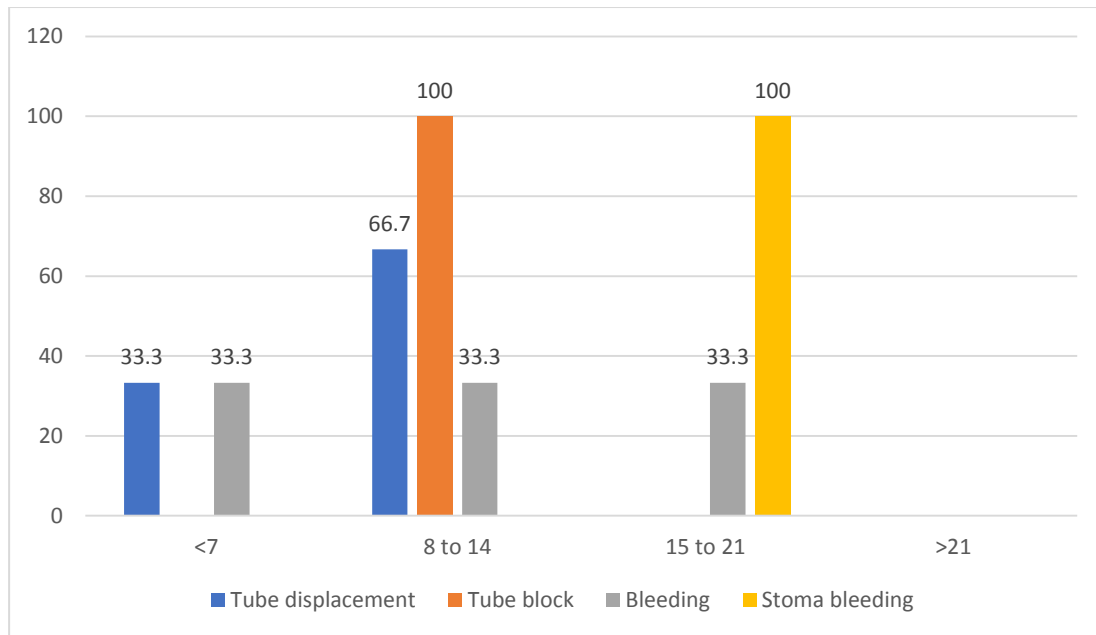


Fig: Immediate and Intermediate Complications among the study participants.

Table 11: Day of weaning from Mechanical ventilation after tracheostomy among the study participants

S no	Tracheostomy done (days)	Day of weaning		P value
		Mean	SD	
1	≤7 (Early)	6.57	4.48	<0.001
2	8 to 14 (Late)	13.43	6.21	
3	15 to 21 (Late)	13.78	6.37	
4	>21 (Late)	19	12.72	

- The day of weaning from mechanical ventilation was earlier among those who had early tracheostomy than those with late tracheostomy and they are statistically significant.

- The mean day of weaning was 6.57, 13.43, 13.78 and 19 among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively.

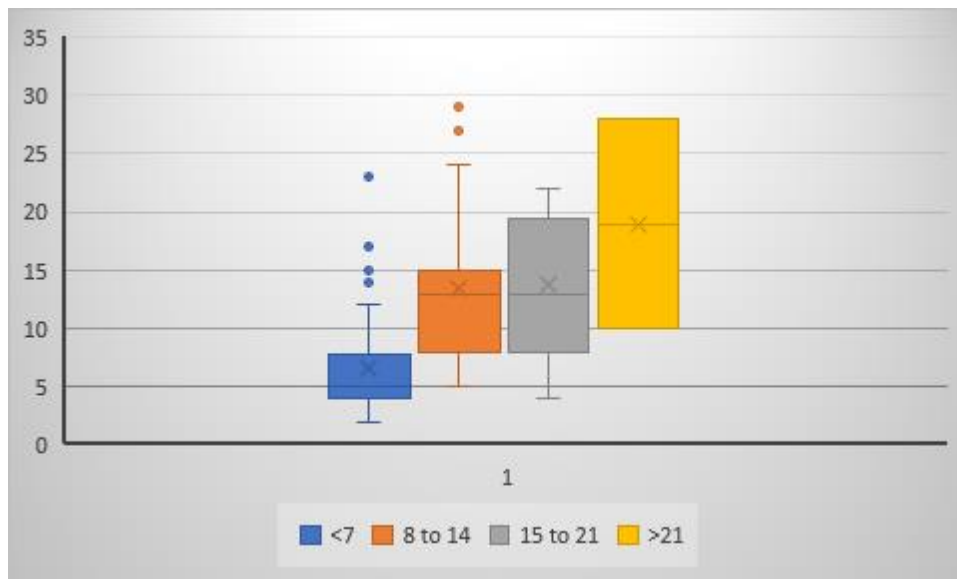


Fig: Mean day of weaning among the study participants

Table 12: Day of metallic tube change among the study participants

S no	Tracheostomy done (days)	Day of metallic tube change		P value
		Mean	SD	
1	≤ 7 (Early)	9.00	5.37	<0.001
2	8 to 14 (Late)	16.93	6.51	
3	15 to 21 (Late)	19	6.74	
4	>21 (Late)	21.5	12.02	

- The day of metallic tube change was earlier among those who had early tracheostomy than those with late tracheostomy and they are statistically significant.

- The mean day of metallic tube change was 9.09, 16.93, 19 and 21.5 among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively

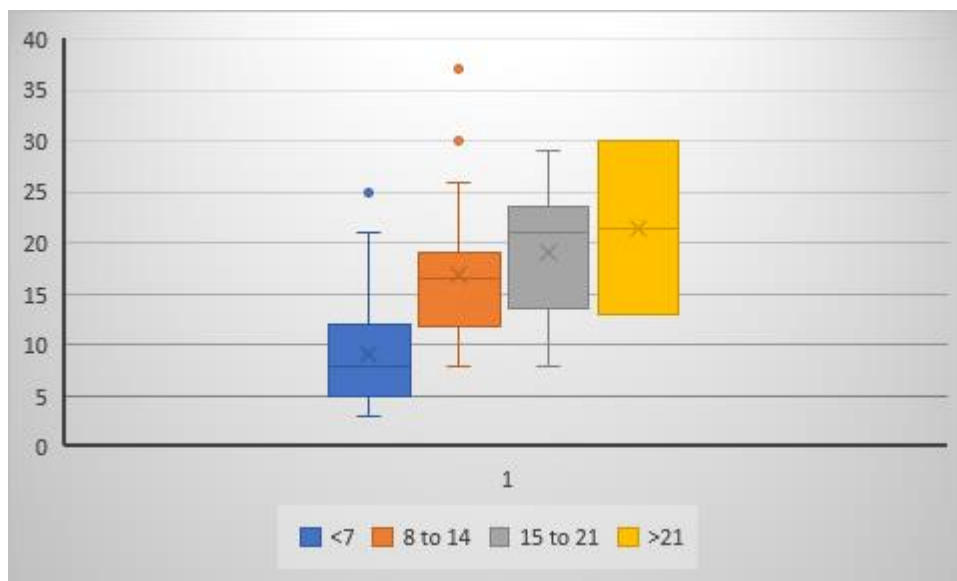


Fig: Day of metallic tube change among the study participants

Table 13: Day of transfer out from ICU among the study participants

S no	Tracheostomy done (days)	Day of transfer out from ICU		P value
		Mean	SD	
1	≤ 7 (Early)	9.09	6.16	<0.001
2	8 to 14 (Late)	17.37	5.64	
3	15 to 21 (Late)	21	7.31	
4	>21 (Late)	25	14.14	

- The day of transfer out from ICU was earlier among those who had early tracheostomy than those with late tracheostomy and they are statistically significant.

- The mean day of transfer out was 9.09, 17.37, 21 and 25 among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively.

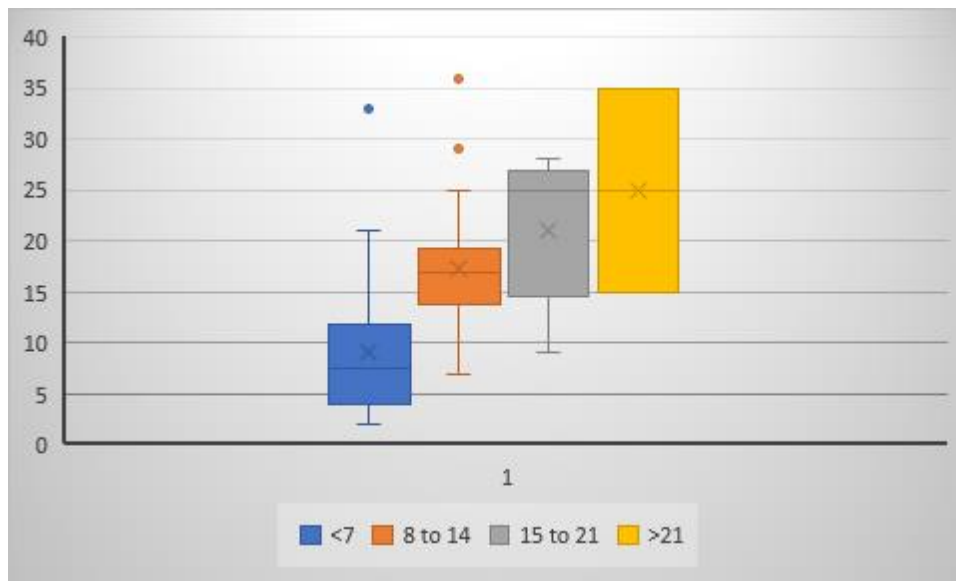


Fig: Day of transfer out from ICU among the study participants

14. Table: Day of decannulation and strapping after tracheostomy among the study participants

S no	Tracheostomy done (days)	Day of decannulation and strapping		P value
		Mean	SD	
1	≤ 7 (Early)	12.05	6.01	<0.001
2	8 to 14 (Late)	20.33	6.65	
3	15 to 21 (Late)	24.44	9.83	
4	>21 (Late)	27.50	14.84	

- The day of decannulation and strapping of tracheostomy stoma was earlier among those who had early tracheostomy than those with late tracheostomy and they are statistically significant.

- The mean day of decannulation and strapping of tracheostomy stoma was 12.05, 20.33, 24.44 and 27.50 among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively.

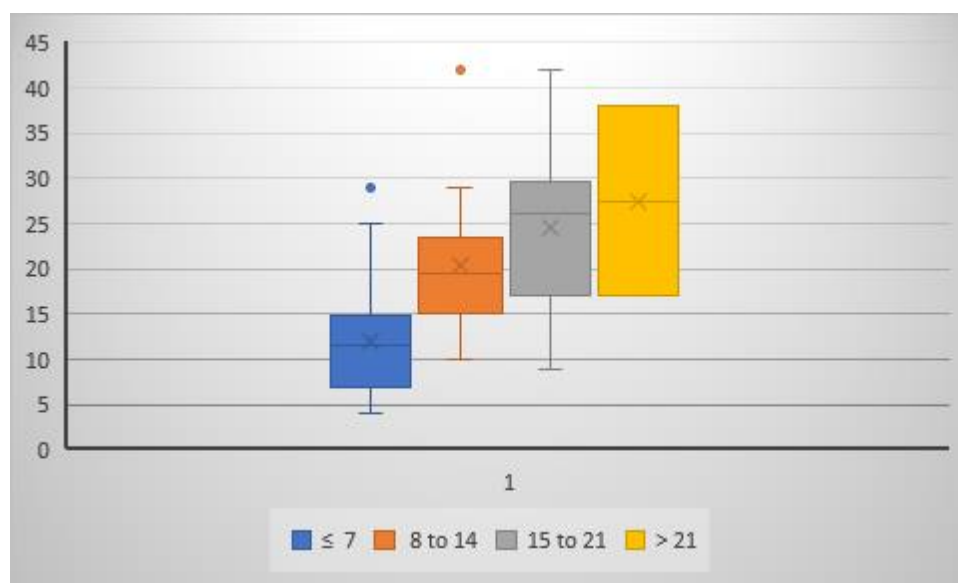


Fig: Day of decannulation and strapping after tracheostomy among the study participants

Table 15 : Day of discharge after tracheostomy among the study participants

S no	Tracheostomy done (days)		Day of discharge		P value
			Mean	SD	
1	≤ 7	(Early)	14.23	7.53	<0.001
2	8 to 14	(Late)	21.77	6.25	
3	15 to 21	(Late)	26.56	10.05	
4	>21	(Late)	31.5	17.67	

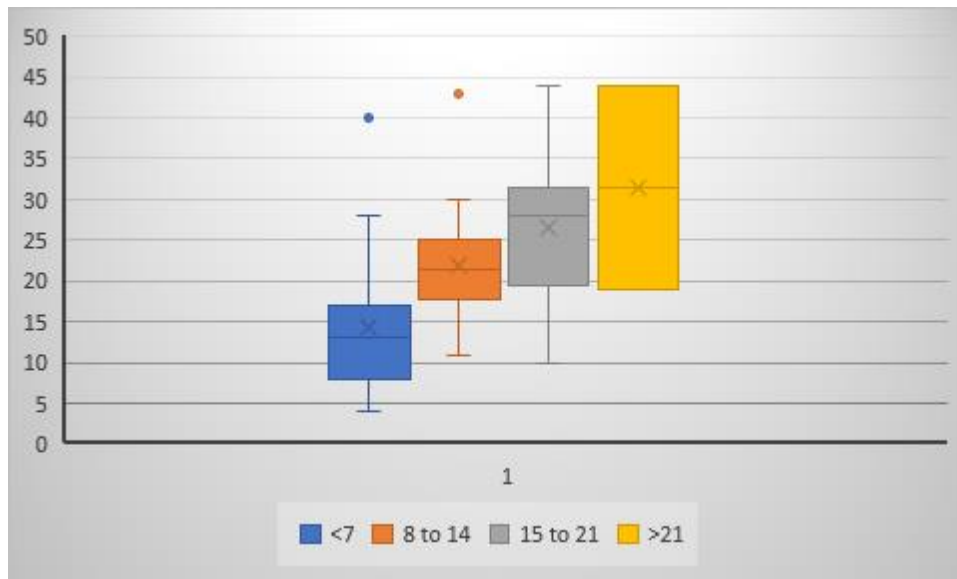


Fig: Mean day of discharge among the study participants

- The mean day of discharge after undergoing tracheostomy among the study participants in early tracheostomy patients was significantly less than late tracheostomy group.
- The mean duration of hospital stay among the patients where 18.78, 30.74, 38.75 and 64.5 for ≤ 7 days, 8 to 14 days, 15 to 21 and > 21 days respectively. this data was found to be statistically significant.

Table 16: Total duration of hospital stay from the day of admission among the study participants

S no	Tracheostomy done (days)		Day of discharge		P value
			Mean	SD	
1	≤ 7	(Early)	18.04	7.66	<0.001
2	8 to 14	(Late)	30.74	7.41	
3	15 to 21	(Late)	40.83	10.59	
4	>21	(Late)	52	22.62	

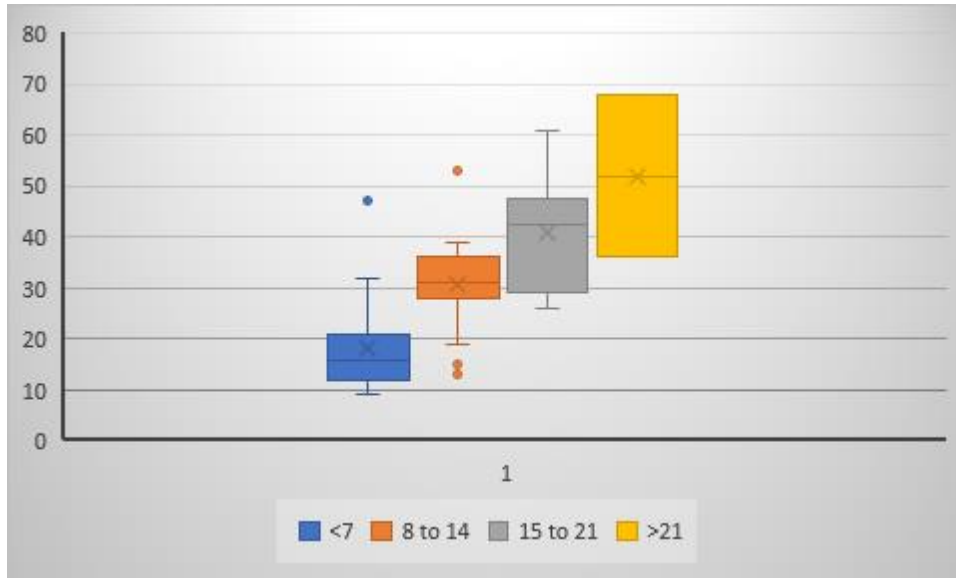


Fig: Total duration of hospital stay

- The total duration of hospital stay in early tracheostomy patients was significantly less than late tracheostomy group.
- The mean duration of hospital stay among the patients where 18.78, 30.74, 38.75 and 64.5 for ≤ 7 days, 8 to 14 days, 15 to 21 and > 21 days respectively. this data was found to be statistically significant.

Table 17: Distribution of outcome according to the age of the study participants

S no	Age (years)	Outcome						P value
		Improved		Died		Complication		
		N	%	N	%	N	%	
1	<20	3	4.8	1	6.7	0	0	0.801
2	21-30	16	25.8	1	6.7	7	30.4	
3	31-40	14	22.6	6	40	7	30.4	
4	41-50	8	12.9	2	13.3	2	8.7	
5	51-60	13	21	4	26.7	5	21.7	
6	>61	8	12.9	1	6.7	2	8.7	

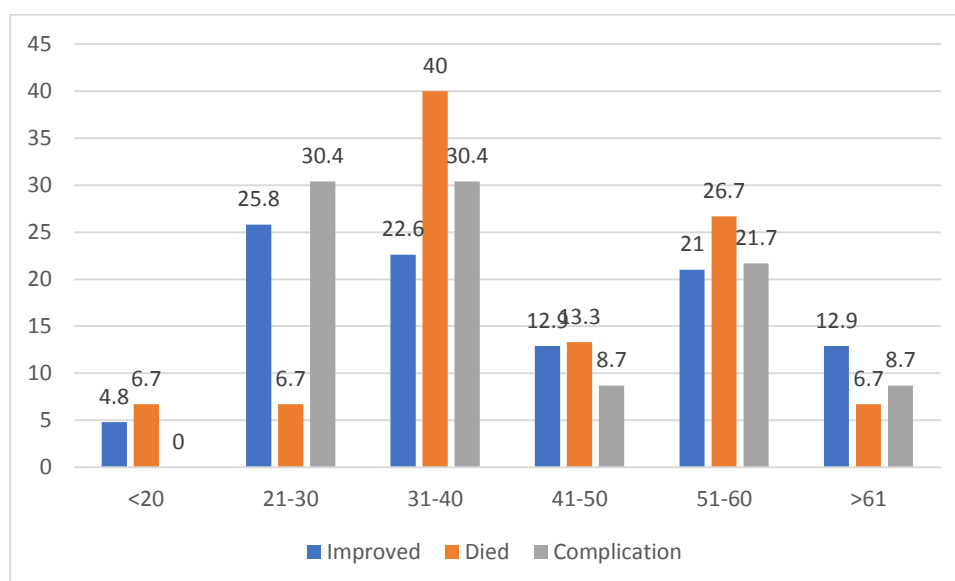


Fig: Distribution of outcome according to the age of the study participants

Table 18: Distribution of outcome according to the diagnosis among the study participants

S no	Diagnosis	Outcome						P value
		Improved		Died		Complication		
		N	%	N	%	N	%	
1	Medical	12	19.4	2	13.3	6	26.1	0.936
2	Neurological	14	22.6	5	33.3	6	26.1	
3	RTA	3	4.8	1	6.7	1	4.3	
4	Toxicology	33	53.2	7	46.7	10	43.5	

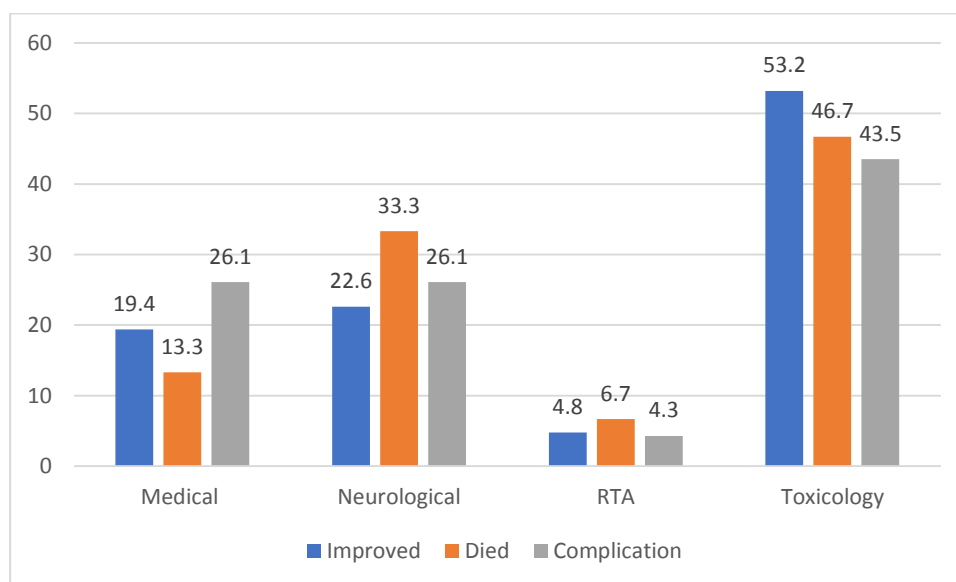


Fig: Distribution of outcome according to the diagnosis among the study participants

Table 19 : Follow up visit on 1 month after discharge among the study participants.

S no	Tracheostomy done (days)	Videolaryngoscopy				P value
		Normal		Complication		
		N	%	N	%	
1	≤7 (Early)	44	60.3	0	0	<0.001
2	8 to 14 (Late)	25	34.2	5	41.7	
3	15 to 21 (Late)	3	4.1	6	50	
4	>21 (Late)	1	1.4	1	8.3	

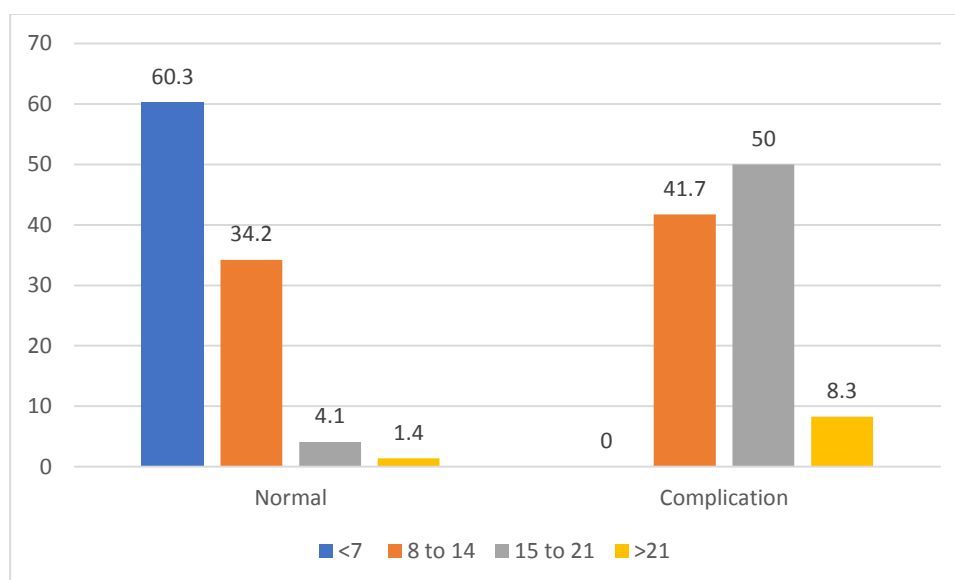


Fig: Video laryngoscopy at 1 month

- Among those who developed complications, majority had underwent late tracheostomy, which is statistically significant.
- The major complication noted were 3 patients who had developed Subglottic stenosis , i.e.,1 patient in late tracheostomy group of 8 – 14 days duration and 2 patients in 15 to 21 days duration group .

- A total of 4 patients had developed Tracheal stenosis out of which 1 patient was from 8 to 14 days duration group, 2 patients were from the 15 to 21 days duration group and 1 patient from the > 21 days duration group.

Table 20 : Follow up at 1 month after discharge among the study participants.

(VIDEOLARYNGOSCOPY)

S.no	Tracheostomy done (days)	Video laryngoscopy									
		Normal		Intubation granuloma (Glottic Injury)		Supraglottic mucosal congestion (Supraglottic injury)		Subglottic stenosis		Tracheal stenosis	
		N	%	N	%	N	%	N	%	N	%
1	≤7 (Early)	44	60.3	0	0	0	0	0	0	0	0
2	8 to 14 (Late)	25	34.2	2	50	1	100	1	33.3	1	25
3	15 to 21 (Late)	3	4.1	2	50	0	0	2	66.7	2	50
4	>21 (Late)	1	1.4	0	0	0	0	0	0	1	25

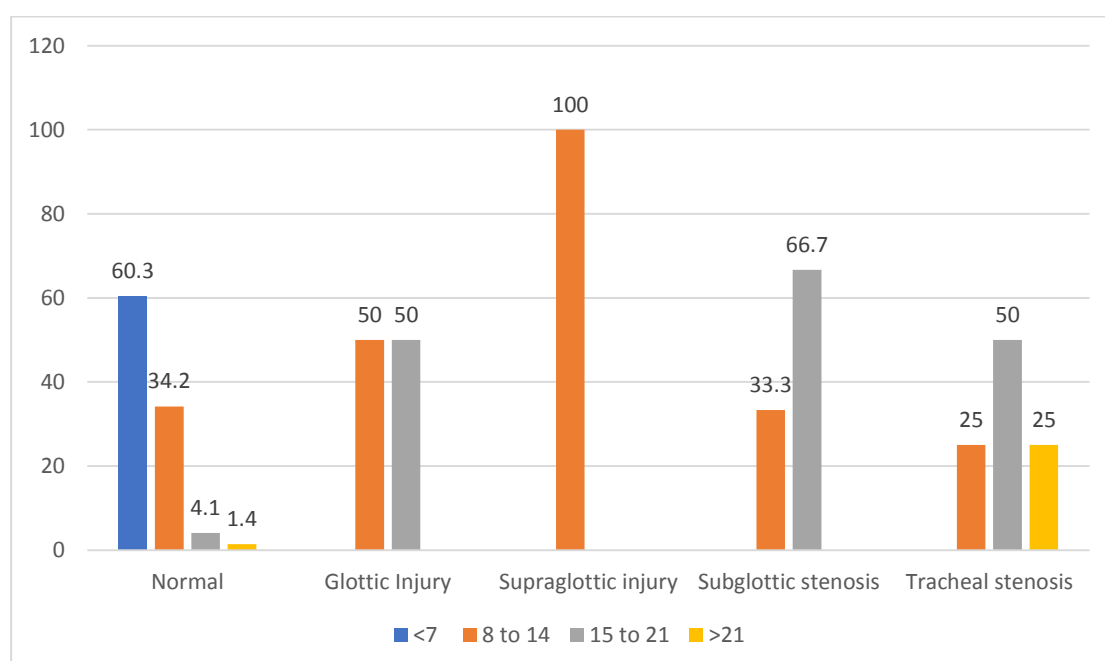


Fig: Video laryngoscopy at 1 month after discharge among the study participants

- 4 Patients had developed Intubation Granuloma in the Late tracheostomy group.
 - 8 to 14 days - 2 patients.
 - 15 to 21 days – 2 patients.

- 1 patient had Supraglottic Mucosal congestion and edema in the 8 to 14 days group.

- Subglottic stenosis was noted in 3 patients on follow up visit.
 - 8 to 14 days - 1 patient.
 - 15 to 21 days – 2 patient.

- Tracheal stenosis was noted in 4 patients on follow up visit.
 - 8 to 14 days - 1 Patient.
 - 15 to 21 days – 2 Patient.
 - >21 days – 1 Patient.

Table 21 : Follow up visit at 6 months among the study participants.

(VIDEOLARYNGOSCOPY)

S no	Tracheostomy done (days)	Videolaryngoscopy				P value
		Normal		Complication		
		N	%	N	%	
1	≤7 (Early)	44	53	0	0	0.525
2	8 to 14 (Late)	29	33.7	1	100	
3	15 to 21 (Late)	8	10.8	1	0	
4	>21 (Late)	2	2.4	0	0	

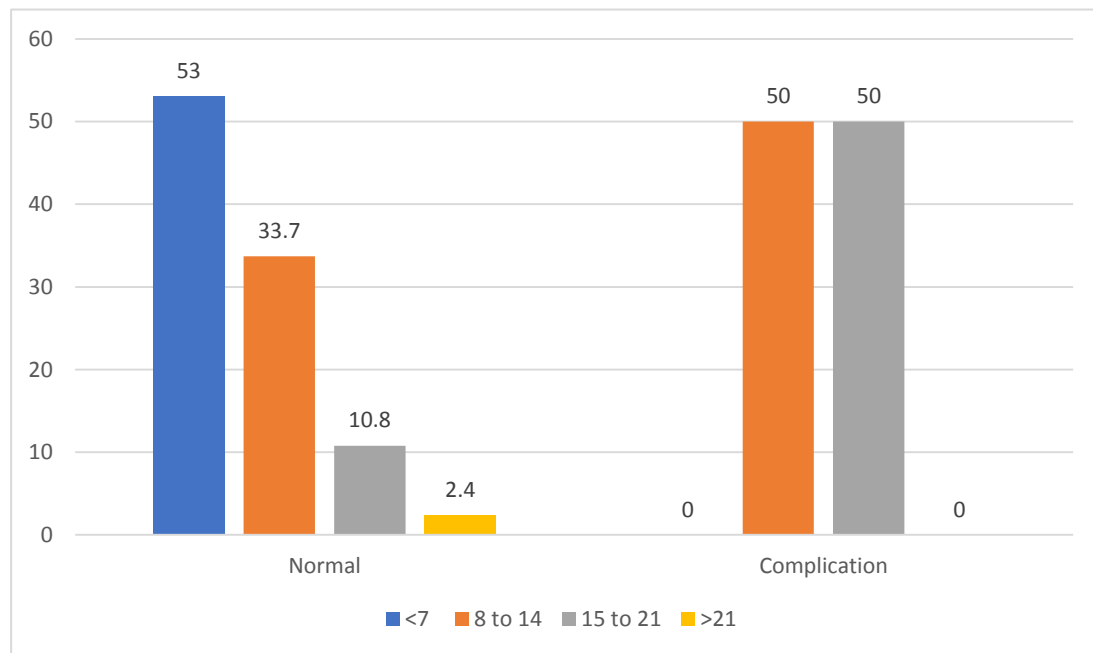


Fig: Video laryngoscopy at 6 months

Table 22 : Video laryngoscopy at 6 months among the study participants

S.no.	Tracheostomy done (days)	Videolaryngoscopy									
		Normal		Glottic Injury		Supraglottic injury		Subglottic stenosis		Tracheal stenosis	
		N	%	N	%	N	%	N	%	N	%
1	≤7 (Early)	44	53	0	0	0	0	0	0	0	0
2	8 to 14 (Late)	29	33.7	1	100	0	0	0	0	0	0
3	15 to 21 (Late)	8	10.8	0	0	0	0	1	100	0	0
4	>21 (Late)	2	2.4	0	0	0	0	0	0	0	0

- Out of 4 patients who developed Intubation granuloma in the late tracheostomy group, 3 patients had the lesions resolved by conservative management.
- 1 patient had persistence of the lesion on the 6 month of follow up visit.
- 1 patient who had Supraglottic mucosal congestion and edema during first followup visit ,the lesion was found to have resolved spontaneously by the 6th month follow up visit.
- Among the late tracheostomy group 3 patients who had Subglottic stenosis, 2 patients had underwent surgical treatment and recovered from it , while 1 patient was on treatment in the 6th month follow up visit.
- All the 4 tracheal stenosis in the late tracheostomy group had underwent tracheal resection anastomosis and tracheal reconstruction surgery and had recovered from it by the 6th month follow up visit.

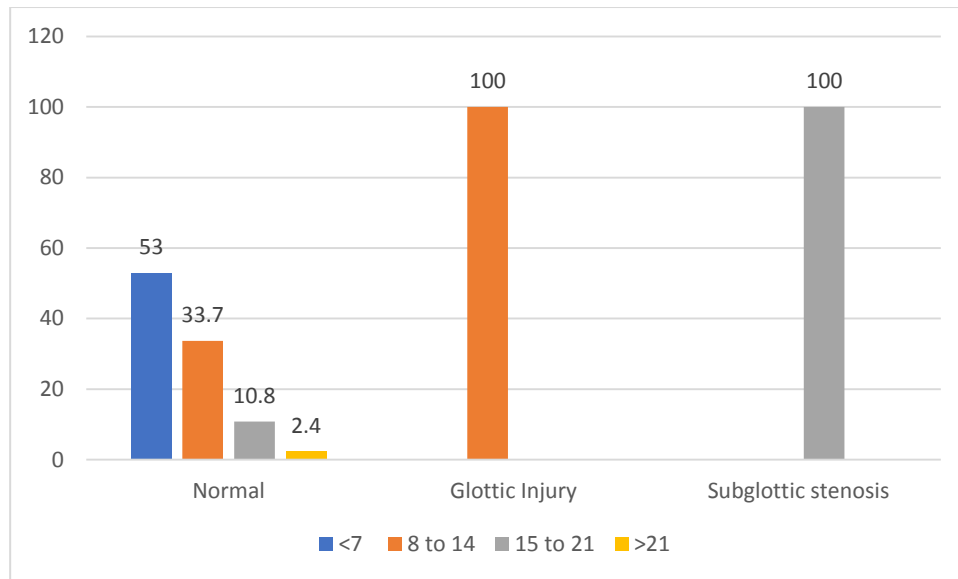


Fig: Video laryngoscopy at 6 months among the study participants

Table 23 : Difference between the two Videolaryngoscopy.

S. No	Tracheostomy done (days)	Videolaryngoscopy									
		Normal		Glottic Injury		Supraglottic injury		Subglottic stenosis		Tracheal stenosis	
		VDL 1	VDL 2	VDL 1	VDL 2	VDL 1	VDL 2	VDL 1	VDL 2	VDL 1	VDL 2
1	≤7 (Early)	44	44	0	0	0	0	0	0	0	0
2	8 to 14 (Late)	25	29	2	1	1	0	1	0	1	0
3	15 to 21 (Late)	3	8	2	0	0	0	2	1	2	0
4	>21 (Late)	1	2	0	0	0	0	0	0	1	0

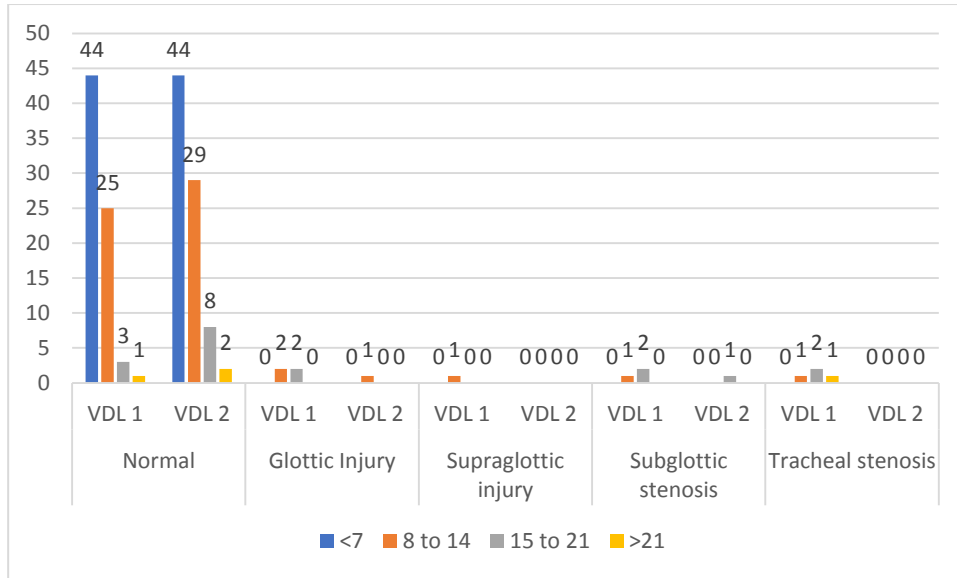


Fig: Difference between the Videolaryngoscopy.

Table 24 : Outcome among the study participants

S no	Tracheostomy done (days)	Total participants	Outcome						P value
			Improved		Died		Complication		
			N	%	N	%	N	%	
1	≤7 (Early)	51	42	95.5	7	13.72	2	4.5	<0.001
2	8 to 14 (Late)	35	18	60	5	14.3	12	40	
3	15 to 21 (Late)	12	1	11	3	25	8	88.9	
4	>21 (Late)	2	1	50	0	0	1	50	

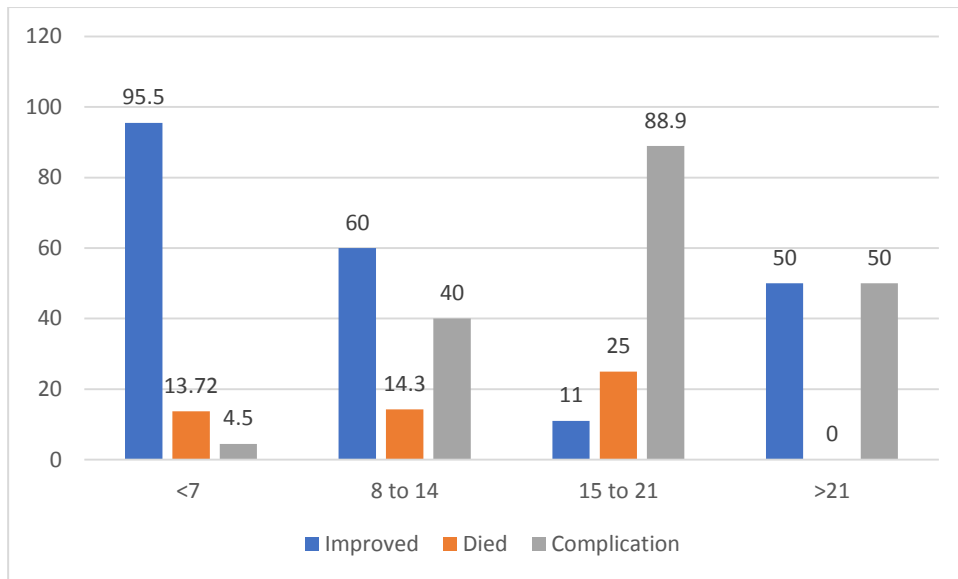


Fig: Clinical Outcome among the study participants

- The total participants taken up for the study was 100.
 - ✓ Early tracheostomy group (≤ 7 days) = 51 Patients had underwent tracheostomy.
 - ✓ Late tracheostomy group : Total patients = 49 Patients had underwent tracheostomy.
 - ✓ Late tracheostomy group is divided into 3 groups :
 - 8 to 14 days of intubation - 35 patients had under went tracheostomy.
 - 15 to 21 days of intubation - 12 patients had underwent tracheostomy.
 - >21 days of intubation - 2 patients had underwent tracheostomy.

Early tracheostomy (≤ 7 days) :

- 42 patients had recovered without any complications in early tracheostomy group (≤ 7 days)
- 2 patients had developed immediate and intermediate complications i.e ., 1 patient had tracheostomy tube displacement and 1 patient had intraoperative bleeding during tracheostomy.

- No late complications related to Endotracheal intubation and tracheostomy were noted in early tracheostomy group.
- 7 patients in early tracheostomy group had died during ICU admission while on Mechanical ventilator support as a consequence of the underlying illness of the patient that had required ICU admission and the patient's comorbidities.

Late tracheostomy :

- Out of 35 patients in late tracheostomy (8 to 14 days) group ., 18 patients had recovered without any complications.

❖ 8 to 14 days group (Late tracheostomy)

- Among 8 to 14 days category in the late tracheostomy group , 7 patients had developed immediate and intermediate complications i.e ., 2 patient had tracheostomy tube displacement , 4 patients had tracheostomy tube block and 1 patient had intraoperative bleeding during tracheostomy.
- Late complication among 8 to 14 days category was noted among 5 patients , i.e.,2 patients had glottic injury (Intubation granuloma) ., 1 patient had supraglottic mucosal congestion and edema ., 1 patient had developed subglottic stenosis and 1 patient had tracheal stenosis.
- 5 patients in late tracheostomy group (8 to 14 days category) had died during ICU admission while on Mechanical ventilator support as a consequence of the underlying illness of the patient that had required ICU admission and the patient's comorbidities.

❖ 15 to 21 days group. (Late tracheostomy)

- Out of 12 patients in late tracheostomy (15 to 21 days) group 1 patients had recovered without any complications.

- Among 15 to 21 days group , 2 patients had developed immediate and intermediate complications i.e ., 1 patient had intraoperative bleeding during tracheostomy and 1 patient had stoma bleeding.
- Late complication among 15 to 21 days group : 6 patients had developed late complications (i.e.,) 2 patients had glottic injury (Intubation granuloma) ., 2 patient had developed subglottic stenosis and 2 patient had tracheal stenosis.
- 3 patients in late tracheostomy group (15 to 21 days) had died during ICU admission while on Mechanical ventilator support as a consequence of the underlying illness of the patient that had required ICU admission and the patient's comorbidities.

❖ **>21 Days group (Late tracheostomy)**

- Out of 2 patients in late tracheostomy (>21 days) group 1 patients had recovered without any complications.
- Among > 21 days group , no immediate and intermediate tracheostomy complications was noted.
- Late complication among >21 days group : 1 patient had developed tracheal stenosis.

Among the late complication

✓ **Tracheal stenosis : 4 patients.**

- 3 patients – Toxicology related diagnosis. (Organophosphorus poisoning) among the 3 patients, one patient had grade II tracheal stenosis and the other two patients had grade III tracheal stenosis.

- 1 patient was undergoing treatment for neurological condition (NMDA positive autoimmune encephalitis) and the patient had grade III tracheal stenosis.
- ✓ **Subglottic stenosis : 3 patients.**
- 1 patient was undergoing treatment for Neurological condition (CVA) had grade II subglottic stenosis
- 2 patient were undergoing treatment for Medical condition. (1 patient was had diagnosis of Community acquired pneumonia with Septicaemia and another patient had diagnosis of Pyrexia of unknown origin Septic Encephalopathy / Hypoxemia / respiratory failure) and both the patients had grade III subglottic stenosis.
- **The Results based on the clinical outcome of the study participants were statistically significant.**





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 17

UCT NECK 17

Name: *Rishikanya* age *14y* sex *female*

Short segment stenosis in the subglottic region just above tracheotomy site for a length of 3cm and with narrowed diameter of 2cm. No enhancing granulation tissue/growth noted.

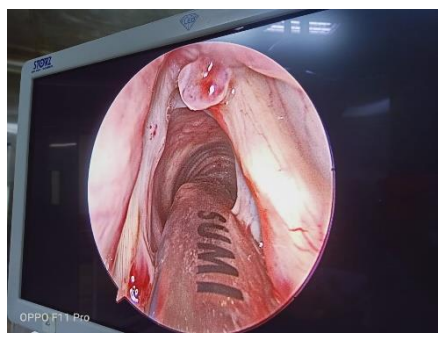
PHARYNX & LARYNX:
 Pharyngeal pouches appear normal on both sides. Medial and lateral plicae are normal and strap head of temporalis muscle appear normal on both sides.
 Cricoid cartilage and fossa of Rosenmüller appear normal on both sides.
 Base of skull and nasopharynx are normal.
 The epiglottis and pyriform fossa are normal. Valleculae are normal.
 Folds and true vocal cords appear normal.

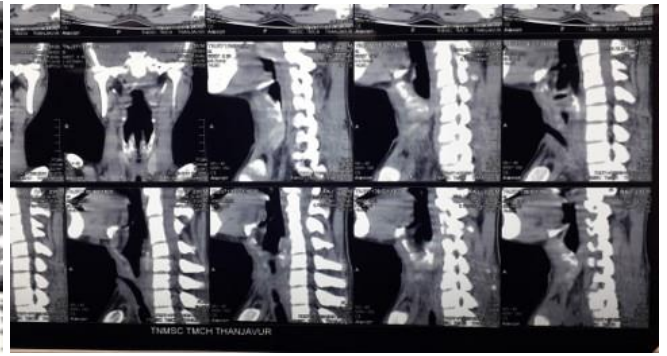
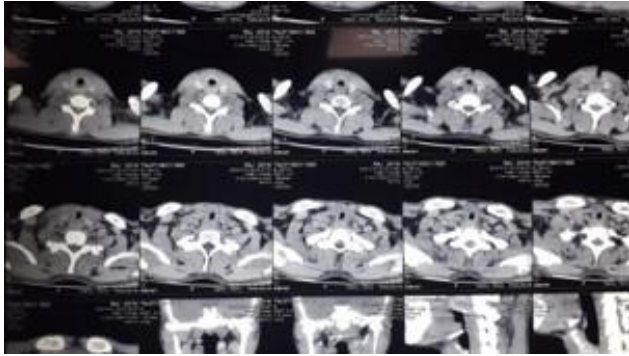
NECKSPACE:
 Retropharyngeal space, retropharyngeal space and parapharyngeal space are normal. The prevertebral space and subglottic space are normal.
 The parotid space, submandibular space and sublingual space are normal.
 No evidence of cervical lymph node enlargement.
 Thyroid cartilage, cricoid cartilage and trachea are normal.
 Inferior jugular vein and carotid arteries appear normal on both sides.
 Cervical spine appears normal.

MAXILLARY SINUS:
 Both maxillary sinuses appear normal. No evidence of mucosal thickening. Any erosion of parietal bone. Right maxillary fat appears normal.

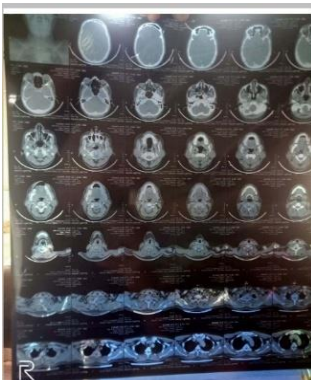
IMPRESSION: *Short segment subglottic stenosis just above tracheotomy site.*

(RADIOLOGIST)

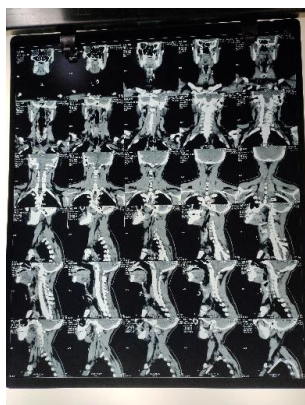




Ct Neck-
 - 40 Soft tissue thickening @ trachea (edema)
 - Significant laryngeal narrowing noted at tracheostomy stoma length about 120mm. No extra tracheal wall @ appearance & no 40 deformity.
 - Oropharynx @
 - 20: Normal appearance



TAMILNADU MEDICAL SERVICES CORPORATION
 RAJAHMUNDRAM DISTRICT HOSPITAL
 CT NECK
 Patient: [Name], Age: 45, Sex: M, Date: 15/11/2023
 Indication: [Text]
 Findings: [Text]
 Impression: [Text]



DISCUSSION

- With improvements and advancement in critical care medicine, many patients subsist the initial periods of critical illness, like trauma, acute respiratory failure, extensive surgeries and are in need of prolonged mechanical ventilation. Hence, many patients are requiring tracheostomy to replace the endo laryngeal intubation in ICU.
- The present study was done with the objective to define optimum time to carry out elective tracheostomy, to assess the incidence, indications, timing of the procedure complications and tracheostomy's impact on patients in intensive care units the median plane
- To study the effectiveness of tracheostomy in reducing the duration of mechanical ventilation and hospital stay and to study the complications (early and late) associated with tracheostomy.
- The present study has shown that mean age of the study participants was 41.60 ± 14.17 years and majority of the study participants contributing to the study were males. 51%, 35%, 12% and 2% of the study participants had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively. Majority of the study participants were male participants. 69 male and 31 female participants.
- Similarly in a study done by Sanabria A et al⁵⁰, it was shown that majority of the study participants were males, with median age of 59 years.
- Correspondingly in a study by Mahafza T et al⁵¹, among the 106 patients, 70% were males with the mean age of 46.5 years.
- Likewise in a study done by Charra B et al⁵², the mean age of the study participants in ICU was 41 years.
- The present study has shown that the mean GCS on day 1 was 7.12, 7.03, 6.5 and 8.00 among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21

days respectively. Similarly the mean GCS on day 3 was 6.46, 6.57, 5.67 and 6.5 among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively.

- In a study done by Lanza DC et al⁵³ did a study to examine the GCS predictive value for tracheostomy. They stated that in patients with GCS less than or equal to 7, the probability of tracheostomy is significantly greater.
- The present study has shown that among those with medical diagnosis, 50% had early tracheostomy and 35%, 15% had tracheostomy at 8 to 14 and 15-21 days respectively. If a patient's ventilation is anticipated to be prolonged, an early tracheostomy should be performed because it offers the advantages of reducing dead space ventilation, decreasing airway resistance, and reducing breathing effort thus promoting the weaning of mechanical ventilation at the earliest allowing the patient to talk, swallow, and reduce the danger of aspiration, a gentle withdrawal from the ventilator is recommended.
- Among those with neurological diagnosis, 40% had early tracheostomy and 40%, 16% and 4% had tracheostomy at 8 to 14, 15-21 and >21 days respectively.
- Among those with RTA 60% had early tracheostomy and 40%, had tracheostomy at 8 days.
- Among those with Toxicology diagnosis, 56% had early tracheostomy and 32%, 10% and 2% had , tracheostomy done at 8 to 14, 15 to 21 and >21 days respectively.
- Similarly a study done by Susanne B.Wilhelms et al (2021) concluded that intoxication was the most common cause for ICU admission.
- Among those who had tracheostomy during lesser than or equal to 7 days, majority 69% had respiratory failure as a reason.

- In late tracheostomy group among those who had tracheostomy on 8 to 14 days, majority had prolonged ventilation.
- Among those with tracheostomy on day 15 to 21, majority had tracheobronchial toileting as the reason for tracheostomy.
- Among those with tracheostomy > 21 days prolonged intubation was the reason for tracheostomy.
- Similarly in correlation to our study , a study by Mohammad Waheed El-Anwar et al⁶⁶ in 2017 observed that Prolonged endotracheal intubation is the main indication of tracheostomy being performed.
- The reintubation was higher among those who had late tracheostomy than those with early tracheostomy. early tracheostomy had 17.6 % and late tracheostomy had 54.2% of reintubation incidence.
- Similarly in a study done by Koh WH et al⁵⁴, it was shown that the reintubation rate was approximately 22% in spite of meeting the criteria of weaning.
- The present study has shown that immediate and intermediate complications was higher among those patients with late tracheostomy. The noted common complications were tracheostomy tube obstruction, tracheostomy tube displacement , Intraoperative bleeding and stomal bleeding. Early and late tracheostomy participants had 33.33 % and 66.66 % of immediate and intermediate complications.
- A retrospective study done by Hsu CL et al⁵⁵, it was shown that the most common immediate complication was moderate bleeding in 6.7% and minor bleeding in 28.2%, followed by subcutaneous emphysema in 1.8% and 2 patients had this with bleeding and Tube obstruction was seen in 1.8%.

- The present study showed that the day of weaning was earlier among those who had early tracheostomy than those with late tracheostomy and they are statistically significant. The mean day of weaning was 6.57, 13.43, 13.78 and 19 days among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively.
- Similarly in a study done by Zheng Y et al⁴⁶, it was shown that successful weaning (74.1% vs 55.7%) was significantly higher in early tracheostomy group than in late tracheostomy group.
- The present study showed that the day of metallic tube change was earlier among those who had early tracheostomy than those with late tracheostomy and they are statistically significant. The mean day of metallic tube change was 9.09, 17.37, 21 and 25 among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively.
- The day of decannulation and strapping of tracheostomy stoma was earlier among those who had early tracheostomy than those with late tracheostomy and they are statistically significant. The mean day of decannulation and strapping of tracheostomy stoma was 12.05, 20.33, 24.44 and 27.50 among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively.
- Similarly in a study by Gabriel A. Quiñones-Ossa et al (2020)⁷⁰ they observed that successful decannulation were plugging the tracheostomy tube (80–100%), endoscopic airway patency evaluation (100–30%), swallowing assessment (85–96%), and blue dye test (65–85%) with these criteria that were combined into a single clinical parameter had greater sensitivity (100%) than specificity (82%). In addition, they evaluated other parameters such as voluntary cough, cough reflex, tracheal suction numbers, oxygen saturation, and the level of consciousness these parameters were better in the patients

undergoing early tracheostomy group with the chances of decannulation was better in early tracheostomy group than late tracheostomy group. however they concluded that in general, decannulation is more often individualized based of patient's health condition rather a than protocol based.

- The day of transfer out from ICU was earlier among those who had early tracheostomy than those with late tracheostomy and they are statistically significant.
- The mean day of transfer out was 9.09, 17.37, 21 and 25 among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively.
- The total duration of hospital stay was lower among those who had early tracheostomy than those with late tracheostomy and they are statistically significant. The mean duration of hospital stay was 18.04, 30.74, 40.83 and 52 days among those who had tracheostomy at ≤ 7 , 8 to 14, 15-21 and >21 days respectively.
- Similarly in a study done by Rumbak MJ et al⁴³, it was shown that duration of ICU was 4.8 and 16.2 days among the early and late group respectively.
- A study done by Bickenbach J et al⁴⁵, showed that length of ICU stay was significantly lower among the early group.
- Likewise Jeon YT et al⁴⁸, has shown that length of stay in ICU (31.1 vs 19.9) were significantly higher in late tracheostomy than the early tracheostomy group.
- Correspondingly, Mohamed KA et al⁴⁹, has shown that the mean ICU length of stay was 21 vs 40.14 among the early and late tracheostomy group respectively. The mean hospital stay was also lesser among the early than the late group (34.6 vs 55.6).

- Charles C. L. Tong et al⁶⁷ in a study concluded that Early tracheostomy i.e., done on or before day 7 of MV in ICU patients is associated with earlier ICU discharge, shorter duration of mechanical ventilation, and decreased length of overall hospital stay without affecting mortality
- The present study has shown that the improvement was higher (52.5%) among those who had early tracheostomy.
- Out of the 15 patients who had died, 7 patients had early tracheostomy and 8 patients had late tracheostomy. All the 15 patients had died during ICU admission while on Mechanical ventilator support as a consequence of the underlying illness of the patient that had required ICU admission and the patient's comorbidities.
- Similarly a study done by Rahul k.shah ., M.D., et al in 2012⁷¹ observed that in-hospital mortality is usually due to the underlying illness rather than the tracheotomy. Mortality was higher in older patients
- The major complication seen was glottic injury resulting in Intubation granuloma , subglottic and tracheal stenosis among those had late tracheostomy after a period of prolonged intubation.
- The present study based that video laryngoscopy findings shows that the complication rate was higher among those who had late tracheostomy. The incident of supraglottic mucosal congestion and edema and intubation granuloma was Nil with the early tracheostomy group whereas it was noted among the late tracheostomy and re-intubation patients group.
- Similarly, Rumbak MJ et al⁴³ did a prospective randomized study with 120 patients with the objective to assess the outcome in patients with early tracheostomy when compared to late tracheostomy. The results showed that

the hospital mortality was 31.7% and 61.7% among the early and late group respectively.

- Similarly in a study done by Bickenbach J et al⁴⁵, ICU mortality was higher among the late group than the early and intermediate group. (40.7% vs 24.8%).
- Young D et al⁴⁷ did a trial among critically ill patients with the aim to compare the early versus late tracheostomy in the outcome of the patients. The results showed that 30 days all-cause mortality was 30.8% and 31.5% among the early and late tracheostomy group respectively. 2-year mortality was 51.0% and 53.7% in the early and late tracheostomy group respectively.
- ❖ The study thereby conveys that the performance of a late tracheostomy was associated with lengthy weaning periods, increased duration of hospital stay and increased incidence of complications. Though early tracheostomy group had few complications than late tracheostomy group, all the complication in early tracheostomy group had got resolved. Hence tracheostomy can be done as soon as possible for those who are in need of an anticipated of prolonged mechanical ventilatory support. The main limitations of the study are, the unprecedented onset of COVID 19 pandemic which had an adverse impact on the overall health facility manpower and infrastructure, the treating physician's bias and the patient's or their caretaker 's consent for undergoing tracheostomy allied with the pre-existing co-morbidities of patient, which further confound the decisions regarding the exact timing of tracheostomy.

SUMMARY & CONCLUSION

A COMPREHENSIVE STUDY OF TRACHEOSTOMY IN ICU PATIENTS AND CORRELATION OF TIMING OF THE PROCEDURE WITH COMPLICATIONS was taken up for study. The study population was split into early tracheostomy group and late tracheostomy groups.

Tracheostomy is one of the most common surgical procedure done in intensive care units. From our study we conclude that

1. GCS of less than or equal 7 was observed to be an indicator for patients requiring endotracheal intubation and prolonged mechanical ventilation.
2. Reintubation attempts was observed to be common among those patients who were on prolonged endotracheal intubation and had undergone late tracheostomy i.e., after 7 days of intubation and it was least among the early tracheostomy group. Sudden desaturation, tube block excessive tracheal secretions and a deteriorating GCS level were found to be the common causes for repeated reintubation with endotracheal tubes. This in turn provokes airway injury like supraglottic laryngeal mucosal injury resulting mucosal congestion, supraglottic stenosis, mucosal ulceration and oedema of epiglottis, glottic injury resulting in intubation granuloma, ulceration, subglottic stenosis and tracheal stenosis. Hence the reason for endotracheal tube reintubation should be individualized and staff nurses should be enlightened about the need of frequent tracheobronchial toileting and maintaining a proper position of the endotracheal tube and tracheostomy tube by properly securing it.
3. In the event of Immediate complications intraoperative bleeding has been the single most common complication noted. Tracheostomy tube block, tube displacement and stomal bleeding have been noted in the post-operative period. This can be avoided by imparting adequate knowledge and skill about the management of the complications. Adequate tube suctioning and proper tracheostomy stoma care with regular dressing plays a vital role in the prevention

of these complications.

4. Patients on prolonged intubation who had underwent late tracheostomy i.e., after 7 days of intubation were more prone for airway injuries such as supraglottic mucosal congestion and edema and Intubation granuloma (glottic injury) as a consequence of reintubation attempts. They also ended up in long term complications like tracheal stenosis and subglottic stenosis. Cuffed tubes should be of appropriate size and the cuff pressure to be maintained within or at 20 mmHg. There are cuff pressure monitors available (Cuff manometer), which can be suggested to be used routinely in order to avoid these complications.
5. From our study it has been analysed that tracheostomy performed within 7 days after intubation was associated with shortened duration of mechanical ventilation, reduced duration of ICU admission and hospital stay than those among the late tracheostomy group.
6. Early Tracheostomy (≤ 7 days) is observed to have resulted in earlier weaning off from the Mechanical Ventilation, a finding suggested by more number of ventilator-free days. The possibility of earlier weaning off from Mechanical ventilation, thereby decreasing the exposure of patients to its associated risks, can be attributed as a prime factor responsible for the lesser complications and long-term survival among the patients undergoing early tracheostomy.
7. Tracheostomy can be carried out as soon as the need for a prolonged Mechanical ventilatory support is anticipated.
8. Hence by day 6 to 7 if the patient could not be weaned off from the mechanical ventilatory support and extubated, based on the daily weaning assessment and patient's clinical diagnosis an early elective surgical tracheostomy for the purpose of Mechanical ventilator support can be planned which will result in a better clinical outcome of the patient undergoing intensive care treatment.

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70. Current Status of Indications, Timing, Management, Complications, and Outcomes of Tracheostomy in Traumatic Brain Injury Patients (2020) Gabriel A. Quiñones-Ossa,¹ Y. A. Durango-Espinosa,² H. Padilla-Zambrano,³ Jenny Ruiz,² Luis Rafael Moscote-Salazar,⁴ S. Galwankar,⁵ J. Gerber,⁵ R. Hollandx, Holland,⁵ Amrita Ghosh,⁶ R. Pal,⁷ and Amit Agrawal⁸
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PROFORMA

Name :

Age / sex :

IP number:

Phone number:

Diagnosis:

Date of admission :

GCS on day 1 :

Day of Intubation :

GCS on day 3 :

SBT :

PaO₂ / FiO₂ Ratio:

Respiratory rate :

Rapid Shallow Breathing Index :

Intubation Continued/ Weaned :

Reintubation :

Day of tracheostomy following intubation:

Reason for Tracheostomy Immediate and intermediate complication of tracheostomy :

Day of weaning from ventilator after Tracheostomy:

Day of metallic tube change after tracheostomy:

Day of transfer out from ICU after tracheostomy

Day of decannulation and strapping. :

Day of discharge after tracheostomy :

Outcome :

Followup visit - I (Videolaryngoscopy – 1) :

Followup visit – II (Videolaryngoscopy – 2):

PATIENT CONSENT FORM

Title of the Project : ‘ A COMPREHENSIVE STUDY OF TRACHEOSTOMY IN ICU PATIENTS AND CORRELATION OF TIMING OF THE PROCEDURE WITH COMPLICATIONS ‘

Institution : Upgraded Institute of Otorhinolaryngology,
Madras Medical College,
Chennai – 600003.

Name : _____ Date : _____
Age : _____ IP No. : _____
Sex : _____ Project Patient No. : _____

The details of the study have been provided to me in writing and explained to me in my own language.

I confirm that I have understood the above study and had the opportunity to ask questions.

I understood that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected.

I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

I have been given an information sheet giving details of the study.

I fully consent to participate in the above study.

Name of the subject

Signature

Date

Name of the Investigator

Signature

Date

INFORMATION SHEET

We are conducting ‘**A COMPREHENSIVE STUDY OF TRACHEOSTOMY IN ICU PATIENTS AND CORRELATION OF TIMING OF THE PROCEDURE WITH COMPLICATIONS** ‘ at the Upgraded Institute of Otorhinolaryngology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 600003.

- In this study the optimum time to carry out elective tracheostomy along with the assessment of the incidence, indications, timing of the procedure , outcome of tracheostomy on patients in the intensive care units (ICU) , the effectiveness of tracheostomy in reducing the duration of mechanical ventilation and duration of hospital stay for all patients in the inclusion criteria are analysed.
- At the time of announcing the results and suggestions, name and identity of the patients will be confidential.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of Investigator

Signature of Participant

Date :

ஆராய்ச்சி தகவல் தாள்

ஆய்வு செய்யப்படும் தலைப்பு :

“A COMPREHENSIVE STUDY OF TRACHEOSTOMY IN ICU PATIENTS AND CORRELATION OF TIMING OF THE PROCEDURE WITH COMPLICATIONS”

ஆராய்ச்சியாளர் பெயர் :

பங்கேற்பாளர் பெயர் :

சென்னை ராஜீவ் காந்தி அரசு மருத்துவமனைக்கு, இந்த ஆராய்ச்சியின் நோக்கம்.

நீங்கள் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியால் உங்கள் சிகிச்சைக்கு பாதிப்பு ஏற்படாது என்பதை தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துக்களை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்ளலாம்.

இந்த ஆராய்ச்சியின் முடிவுகளையும் நோயின் தன்மைப்பற்றியும் ஆராய்ச்சியின் போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம்

பங்கேற்பாளர் கையொப்பம்

தேதி:

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு :

“A COMPREHENSIVE STUDY OF TRACHEOSTOMY IN ICU PATIENTS AND CORRELATION OF TIMING OF THE PROCEDURE WITH COMPLICATIONS”

ஆராய்ச்சி நிலையம் : இராஜீவ் காந்தி அரசு பொது மருத்துவமனை மற்றும்
சென்னை மருத்துவக் கல்லூரி,
சென்னை - 600 003.

பங்கு பெறுபவரின் பெயர் :
பங்கு பெறுபவரின் எண். :

உறவுமுறை :

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்ஆய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்ஆய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்மந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும்போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதைப் பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லாத எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்..... இடம்..... தேதி
கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்.....

ஆய்வாளரின் கையொப்பம்..... இடம்..... தேதி

ஆய்வாளரின் பெயர்.....

**INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003**

EC Reg.No.ECR/270/Inst./TN/2013/RR-16
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.VIMAL DASS M,
MS (ENT), Post Graduate,
Upgraded Institute of Otorhinolaryngology,
Madras Medical College &
Rajiv Gandhi Govt. General Hospital,
Chennai-600003,

Dear Dr. VIMAL DASS M,

The Institutional Ethics Committee has considered your request and approved your study titled "**A COMPREHENSIVE STUDY OF TRACHEOSTOMY IN ICU PATIENTS AND CORRELATION OF TIMING OF THE PROCEDURE WITH COMPLICATIONS**"- **NO.20112020**. The following members of Ethics Committee were present in the meeting held on **17.11.2020** conducted at Madras Medical College, Chennai 3.

- | | |
|--|--------------------|
| 1. Prof.P.V.Jayashankar | :Chairperson |
| 2. Prof.N.Gopalakrishnan,MD.,DM., FRCP, Director, Inst. of Nephrology,MMC,Ch | : Member Secretary |
| 3. Prof. K.M.Sudha, Prof. Inst. of Pharmacology,MMC,Ch-3 | : Member |
| 4. Prof. Alagarsamy Jamila ,MD, Inst. of Pathology, MMC, Ch-3 | : Member |
| 5. Prof.Remam Chandramohan,Prof.of Paediatrics,ICH,Chennai | : Member |
| 6. Prof.S.Lakshmi, Prof. of Paediatrics ICH Chennai | :Member |
| 7. Tmt.Arnold Saulina, MA.,MSW., | :Social Scientist |
| 8. Thiru S.Govindasamy, BA.,BL,High Court,Chennai | : Lawyer |
| 9. Thiru K.Ranjith, Ch- 91 | : Lay Person |

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee


Dr.N.GOPALAKRISHNAN, M.D., DM., FRCP,
Member Secretary
Institutional Ethics Committee
Madras Medical College

KEYS TO MASTER CHART

ICU	-	INTENSIVE CARE UNIT
GCS	-	GLASGOW COMA SCALE
DOI	-	DAY OF INTUBATION
DOW	-	DAY OF WEANING
DOD	-	DAY OF DISCHARGE AFTER INTUBATION
DOT	-	DAY OF TRACHEOSTOMY
REASON_TRACH	-	REASON FOR TRACHEOSTOMY
D.O.W.A.TR	-	DAY OF WEANING AFTER TRACHEOSTOMY
D.O.M CHANGE	-	DATE OF METALLIC TUBE CHANGE
D.O.TR	-	DAY OF TRANSFER OUT
D.O.S/D	-	DAY OF STRAPPING AND DECANNULATION
D.O.D.A.T	-	DAY OF DISCHARGE AFTER TRACHEOSTOMY
VDL	-	VIDEOLARYNGOSCOPY

