"BACTERIAL FLORA OF THE RESPIRATORY TRACT FOLLOWING TRACHEOSTOMY IN INTENSIVE CARE UNIT PATIENTS: A ONE YEAR PROSPECTIVE STUDY IN PRABHAKAR KORE HOSPITAL"

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ABBREVIATIONS USED

LRT	:	Lower Respiratory Tract
VAP	:	Ventilator Associated Pneumonia
Et Al	:	Et Alii (Latin; 'And Others')
ICU	:	Intensive Care Unit
MDR	:	Multi- Drug Resistant
i. e	:	Id Est (Latin; 'That Is')
spps	:	Species
GNB	:	Gram Negative Bacteria
PPM	:	Potentially Pathogenic Micro-Organism
EGNB	:	Enteric Gram- Negative Bacilli
MRSA	:	Methicillin -Resistant Staphylococcus Aureus
GNEB	:	Gram -Negative Enteric Bacteria
A.D.	:	Anno Dominic
B.C	:	Before Christ
MV	:	Mechanical Ventilation
ICSOL	:	Intracranial Space Occupying Lesion

OT	:	Operation Theatre
AGNB	:	Aerobic Gram Negative Bacteria
FOB`	:	Fiber optic Bronchoscopy
DM	:	Diabetes Mellitus
ARDS	:	Acute respiratory Distress Syndrome
PVC	:	Poly vinyl Chloride
mnth	:	Month

ABSTRACT

Background: Tracheostomy is a term used to refer the creation of a surgical opening into the trachea. Indications for tracheostomy can be broadly outlined as respiratory obstruction, respiratory failure, respiratory paralysis, retained secretions and reduction of dead space. Tracheostomy offers several advantages like improved physical and psychological comfort, decreased risk of inadvertent extubation, accelerated weaning from mechanical ventilation, decreased time of Intensive Care Unit (ICU) stay before transfer to step-down facilities, and reduced risk of developing ventilator-associated pneumonia. Tracheostomy facilitate weaning by reducing dead space and airway resistance. Ironically by exposing the lower respiratory tract directly to the environment, tracheostomy allows colonization by exogenous bacteria. Bacterial flora following tracheostomy will be assessed which will be helpful in management of tracheobronchial tree infections.

Objective:

To study the pathogen present in tracheostomy site following tracheostomy.

Materials and Methods:

The study was done in I.C.U and Department of Otolaryngology -Head and Neck Surgery in KLES Dr. Prabhakar Kore Hospital 30 cases of tracheostomies from January 2020 to December 2021

- A total of three samples of tracheal aspirate will be collected using a sterile suction tip catheter from each patient for the study.
- 1st sample – during tracheostomy
- 2nd sample – 5th day of tracheostomy

- 3rd sample – 10th day of tracheostomy

- For the collection of samples sterile suction catheter will be introduced into trachea and suctioning will be done to clear secretions. Under aseptic precaution tip of suction catheter will be cut and placed in sterile container and will be sent for bacterial culture for bacteriological analysis.

Cultural results will be followed up and noted down.

Result:

We studied 30 patients who underwent tracheostomy for various indications and tracheal aspirates were collected on day 0, 5, 10. Most common age group was between 18-30 comprising (36.67 %) of cases and second most common was 51-60 (23%).The present study most of the cases did not harbour organism immediately after the procedure but as the day of tracheostomy increases there was increased growth of Gram negative bacteria like Pseudomonas aeruginosa, Klebsiella pneumonia and Acenitobacter spps .On day 0, 26% of patients showed no growth in tracheal aspirate as compared to 93% on day 5 following tracheostomy. No growth of St aureus was noted on days 0, 5 with 1 (3.3%) on day 10. The isolation of Aerobic Gram-Negative bacteria (AGNB) increased from 21 (75%) on day 1 to 25 (86%) on day 10 of the aspirate.

Conclusion:

Colonization following Tracheostomy is very much evident regular monitoring of these patients are important with tracheal aspirate to see the pattern of growth and to start antibiotics accordingly and to prevent complication related to trachea-bronchial tree

Key Words: Tracheostomy, Bacterial flora , Bioflim

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INTRODUCTION

Surgical opening into trachea is called tracheostomy[1]. Conditions like respiratory blockage, failure of respiratory system, paralysis of respiratory system, collected secretions in lungs, and to minimize dead space are reasons for tracheostomy. Tracheostomy causes improvement in physical and mental status, reduces the risk of reckless extubation, accelerates removal from Mechanical Ventilation, reduced stay in Intensive care unit (icu) before transfer to step-down facilities, and promising results in preventing ventilator-associated pneumonia. [2].

By minimizing dead space and airway resistance, as well as increasing secretion clearance, a tracheostomy may help with weaning. This lessen the risk of inspissated mucus obstructing the tube, reduces patient distress, reduces sedation needs decreases the risk of aspiration due to enhanced glottis function [3].

Ironically exposure of airway directly to external habitat allows growth by exogenic bacteria [4].

Oral cavity colonization of by bacteria in addition to aspiration of depreciated oral cavity secretions and seepage around the endotracheal tube into airway impacts as colonization. Nosocomial pneumonia or tracheobronchitis is long -term complication of ventilated patients. [5]

During suctioning, ventilator circuit manipulation, and bronchoscopy by healthcare professionals, there is an elevated risk of nosocomial colonization. Antimicrobial therapy is directed against possible bacterial pathogens in the treatment of tracheobronchial tree infections. The growing incidence of anaerobic bacteria in tracheo-bronchial tree infections has provided better understanding of their involvement in the disease process and a re-examination to treat it properly [6].

In this study, nature of bacterial flora of tracheostomy site after tracheostomy, as well as change in bacterial flora over time, will be evaluated, which will aid in the documentation, plan choice of antibiotic and prevent trachea-bronchial tree and tracheostomy wound infections.

OBJECTIVE

To study the pathogen present in tracheostomy site following tracheostomy.

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REVIEW OF LITERATURE

It is not possible to maintain a sterile lower airway in a patient with tracheostomy Anatomically, a tracheostomy wound is an abnormality. A low-grade mucocutaneous irritation is caused by the tracheostomy tube. The pH of lower airway secretions is raised, and the trachea's natural posture is altered. In the presence of microbial exposure, tracheostomy bypasses the physiologic filter mechanism, reducing bacterial invasion into the lower airway. Rather than the oropharynx as a location of acquisition, the tracheostomy wound and the channel produced indicate an attraction for microbes.

- A study in 1992 by Rubenstein JS et al endogenous route of colonization of lower airway occurs from oropharynx. Exogenous route is directly into the trachea via the endotracheal tube or the tracheostomy.
- A study in 2002 by Morar P et al in Liverpool, they showed that changing the mode of ventilation from endotracheal to tracheostomy increased the colonization of lower airways (87%).
- In a study conducted by McCaleb R et al [7] was a retrospective study of tracheostomy patients most prevalent organism recovered in the 93 patients they studied was P. Aeruginosa (90.3 percent), with Gram-negative organism predominating. Methicillin-resistant S. Aureus was found in 55.9% of the research participants. The methicillin-sensitive S. Aureus was the first organism to be isolated after tracheostomy insertion. According to the researchers, the study gives an updated summary of the range of possible pathogens identified from respiratory cultures of pediatric individuals with long-term tracheostomies.

- A study by Rao MH et al [1], studied a sample size of forty patients which compared the bacterial growth of the oropharynx and lower airway during tracheostomy to the bacterial growth of lower airway following change of tube in individuals who had tracheostomy. They discovered that foreign bacteria, such as Enterobacter (27 percent), Acinetobacter baumanii (22 percent), and E. Coli, colonize the lower respiratory tract following tracheostomy (20 percent). They came to the conclusion that tracheal colonization at the time of tracheostomy is unimportant which has no bearing on tracheal colonization after tracheostomy.

- A study was done by Xiaoling Qi et al [9], which was prospective study in intensive care unit (ICU) which was done to establish relationship between microbes and prognosis of patients in LRT infection with P. Aeruginosa in VAP patients They concluded that lower respiratory tract microbial composition varied P. Aeruginosa, VAP patients, forming separate two groups that were identical with primary disease.

- A study from April 2008 to February 2009 by Koirala P et al [8], which was cross-sectional study of fifty patients of which tracheal aspirates was collected who had fevers more than 38degree and was debated for bacterial growth. Out of the fifty samples, forty-five sample showed bacterial growth. Study reported startling growth of MDR in tracheal aspirates. Surveillance for source of multidrug-resistant bacteria would be helpful for the interference of infections.

- In a study conducted in Kathmandu in 2010 by Koirala P et al, they found that polymicrobial growth was present in 2/5 of the cases. These are attributed to multiple growths to a defective immune system along with gastro-intestinal colonization[6]

- A study conducted by M. Aswin et al [5], A clinical descriptive study of 21 months duration from Oct 2012 to June 2014. A total of two samples of tracheal aspirate were taken from each patient for the study, one during tracheostomy and the other seven days after tracheostomy, using a sterile suction catheter. There were 130 cases in total who were investigated. They concluded that after a tracheostomy, the lower respiratory tract, which is normally sterile, becomes easily colonized with bacteria, most commonly Gram-negative bacteria such as Pseudomonas aeruginosa and Klebsiella pneumonia. Serial tracheal aspirate cultures should be performed to understand the nature of bacteria and treat infections appropriately.

- A study conducted by Sanders et al [1], between 2007 and 2012, 185 children with a tracheostomy were studied in a database, with 69 of them having chronic bacterial growth status. P aeruginosa was the most often isolated pathogen from tracheostomy cultures, with 49 percent of patients (91/185) growing it at least once. At least once, P aeruginosa coupled with additional gram-negative rods was identified in 63 percent (116/185) of the individuals. They came to the conclusion that more research is needed to establish best practice standards for these patients.

- The study conducted by Tan C-Y, et al [10], which was a retrospective study between January 2002 and December 2016 included 99 patients. This study showed predominance of Gram-negative organisms chiefly P. aeruginosa Second most frequent was S. aureus. Unnecessary antibiotic use among clinicians has led to Bacterial and non-bacterial pneumonia difficult to differentiate clinically.
- A study conducted by M. Lepainteur, et al[12] was single center prospective study between February 2015 and December 2016 which included 77 tracheal aspirates, majority of pathogenic bacteria were found in 90% of cases (69/77) with Pseudomonas aeruginosa most common (32/77, 41%), (34/77, 44%)

Staphylococcus aureus and (22/79, 38%) Serratia marcesens. S. aureus in tracheal aspirate is common in long-term tracheostomized children 13, and no risk factor for S. aureus colonization was detected among all compared items. "Two out of three most common bacteria isolated, P. aeruginosa and S. marcescens, and S. aureus are intrinsically resistant to Amoxicillin + Clavulanic acid, preventing its use in the empiric treatment of lower respiratory tract infection in these people".

Potential Pathogenic Microorganism

Tracheostomized patients get colonized and infected with aerobic gram-negative bacilli, particularly Pseudomonas and Serratia species. Long term tracheostomies have shown growth of enteric gram-negative bacilli (EGNB). Common potentially pathogenic microorganisms (PPMs) isolated from the lower airway in children are Streptococcus pneumoniae, Staphylococcus aureus, and Haemophilus influenza. [13]

The possible reason for this difference between adults and children could be that adults possess limited receptor sites for S aureus and they might be suffering from age related issues and chronic conditions such as lung pathology, DM, alcohol addiction, and carcinomas. In above conditions colonization by aerobic gram-negative bacilli have been found with significantly higher rates[14]. In reaction to these underlying chronic illnesses, macrophages are hypothesised to secrete elastase. Elastase is then released into the saliva, depleting the mucosa of fibronectin and opening up receptor sites for aerobic gram-negative bacteria [22]. Community bacteria, such as S. pneumoniae and S. aureus [15] have attachment sites on fibronectin.

In a study by Niederman MS et al in 1984 the tenacity of specific EGNB for five participants' lower airways Antibiotic therapy focused at Pseudomonas species was used to treat tracheobronchitis[16], which eliminated Pseudomonas species invasion.

- A study in 1984 by Niederman MS et al, out of the 49 tracheal cultures tested EGNB were found in 37 (76%) with 28 of them containing Pseudomonas species. Pseudomonas aeruginosa, P maltophila. In inclusion to Pseudomonas species, the most prevalent isolates at the tracheal location were Enterobacter species and S marcescens[16]. The high prevalence of EGNB is due to bacteria entering the tracheobronchial tree through the gastrointestinal tract, as well as increased abdominal volume, which causes colon bacteria to reflux into lungs.

- Bryant et al conducted a study involving 101 patients in intensive care unit conclusion stated that ninty-four had colonization with potential pathogens lower-airway, most often with P aeruginosa or other EGNB.

- One -year study conducted by Brook in which he collected tracheal cultures of 27 pediatric tracheostomized patients with severe neurological condition, he found that the most common microflora was P. aeruginosa and other EGNB. He also found that when Pseudomonas aeruginosa was detected, the organism stayed longer in the tracheal aspirates than any other organism and was resistant to aminoglycoside therapy.

- In a study conducted by Koirala P et al[8] in 2010 involving 50 cases, Bacterial growth was found in 45 (90%) of the cases. Sixty-seven isolates were found, with 20 (44.4%) of them being polymicrobial P. aeruginosa, enteric Gram-negative bacteria was most common microorganisms (n=27, 40.3%), other organism found was Staphylococcus aureus (n=7, 10 %), Gram-negative bacteria (n=4, 6 %), and Viridans Streptococci (n=2, 3 %)[17].

Biofilms:

Free-flowing bacteria stick quickly to solid medium in aqueous environment which forms fluid channels and network of microcolonies containing bacteria coated with mucus, known as biofilm. They are protected from the host and the environment by the slime covering, which is an exo-polysacchride matrix. Furthermore, antimicrobials have a difficult time penetrating this glycocalyx matrix.[18]

A study conducted in 1996 Sweden by Harlid R et al they showed that patients were infected with one or more potential organism at the stromal spot 83% and trachea 95%. The most prevalent colonising bacteria at these areas were Pseudomonas aeruginosa Staphylococcus aureus and gram-negative enteric bacteria (GNEB) [19].

A study conducted in 1999 Amritsar by Arora U et al bronchial secretions from non-tubercular chest infections from 50 patients were collected through fiber-optic bronchoscopy (FOB) which showed growth for aerobic and anaerobic organisms. 33 (66%) showed positive bacterial growth. Out of 33 , 30 were cultured and showed diverse growth of aerobic and anaerobic micro-organisms. Aerobic bacteria showed majority of growths. Staphylococcus aureus, Pseudomonas and Streptococcus pneumoniae were the major aerobic isolates. In vitro susceptibility tests was also done was. It was found that better competent drug against aerobes was ciprofloxacin and for anaerobes was metronidazole. [20]

A study conducted in 2004 Seattle by Perkins J et, during tube change eleven tracheostomy tubes were studied for biofilms and the exsistence of live bacteria using cono-focal microscopy and staining method. The distal tip, mid-tracheostomy tube, and proximal aperture of tracheostomy tubes were all evaluated for their exterior and internal surfaces. These findings were compared to the cultures of tracheostomy sites and the reasons for tracheostomy dependency. Distal tip of inside side of 10 of 11

tracheostomy tubes, biofilm was discovered.. Biofilms were found in four tubes externally, all in the same area. There was biofilm on the inner side of mid tracheostomy tube site in eight cases, but only one on the internal surface of the proximal tracheostomy tube. Biofilm was confluent in 5 tubes and patchy with signs of microcolony growth in the other 5 tubes at the distal internal tracheostomy tube location. Live bacteria were found in every biofilm. Biofilms were not found in the control tracheostomy tubes. Tracheostomy tube biofilms were found in all tracheostomy site growth and underlying disease states (chronic aspiration and neonatal chronic lung disease). In four cases, tracheostomy site cultures were provided, all of which developed numerous organisms.[21]

A study was conducted in USA by Jarrett WA et alto investigate how bacterial biofilms form on tracheostomy tubes using four discrete tube materials: PVC, silicone, german steel, and sterling silver, and to see if there is a material variance in biofilm creation. Pseudomonas aeruginosa and Staphylococcus epidermidis developed bacterial biofilms on tracheostomy tubes in vitro, according to scanning electron microscopy.[22]

A study conducted in 2009 Pennsylvania by Solomon DH et al tracheostomy tubes were collected from inpatient and outpatient patients in urban medical centre. Cross-sections from tracheostomy tubes were visualized under Laser confocal scanning microscopy and bacteria was cultured and identified. 19 of 21 tracheostomy tubes obtained were cultured for microorganisms, with number of colony forming units (CFUs) and organism present noted and meta-analysis conducted to see if there was a link between them and various clinical factors. Each of the 2 mm pieces contained in the middle of 1 x 10 (6) and 1 x 10(10) CFUs. From culture and speciation, twelve clear-cut bacterial species and one fungus were found. Tubes

obtained from same patient at different dates, the quantity of bacteria isolated and CFUs determined diversified. Biofilms were discovered on tracheostomy tubes collected as early as seven days after implantation in more than 90% of inpatient and outpatient tracheostomy tubes. Despite the fact that the biofilm contained a wide variety of bacteria, laser cono-focal scanning imaging revealed distinct microcolonies that seemed to be mono-species biofilms. Number of colony forming units discovered with frequency of inner cannula modification had a statistically significant inverse relationship [23].

Historical aspects:

This operation was first mentioned by Galen and Arejeus 1st and 2nd centuries A.D. They used a word that meant "to cut the larynx" or to cut the antery" (Anteria aspera) and bronchus all to mean the windpipe.

The procedure of Tracheostomy has evolved over the ages with its evolution characteristically getting segmented into five phases , namely the 'phase of legend' from 2000 B.C. to A.D. 1546; the 'phase of fear' from 1546 to 1833 when very few surgeons dared to take the risk of performing it owing to the adverse outcomes which could affect them professionally; the 'phase of drama' from 1833 to 1932 during which procedure became restricted to emergency settings where the patient was in dire need of it due to acute obstruction; the 'phase of enthusiasm' from 1932 to 1965 when tracheostomy became the surgeon's choice of procedure when he found the need for it; and the 'phase of rationalization' from 1965 to the present[24]

Alexander the Great, according to Homer circa 1000 BC, used is sword to spilt open trachea of a soldier who was suffering from asphyxia. Tracheostomies were well

known in India by the end of the fifth century A.D. (e.g. The Hindu text Sushruta Samhita)

Despite many ethical concerns, it became widely considered as the last hope for people suffering from specific disorders. Guidi developed a unique tracheostomy technique in the 16th century [25].

First pediatric tracheostomy was performed by Habicot in 1620. Tracheostomy gained popularity in the 1800's, but was associated with high mortality and morbidity. Chevalier Jackson standardized the procedure in the early 1900s, demonstrating that if surgery was accomplished properly and careful attention was paid to post-operative management, there was significantly reduction in mortality rate.[25]

The third period begins in 1833 with Trousseau's reported 200 cases of diphtheria remedy. Asphyxia and acute respiratory obstruction made tracheostomy a highly dramatic operation. In the early 1800s, tracheostomies were used to treat children with Diphtheria who had airway inflammation. In 1808, first successful tracheostomy on a kid was done and documented.

A lower tracheostomy procedure, in which the 4th or 5th tracheal ring tracheal incised was introduced in 1909. Chevalier Jackson developed and standardized this operational approach, advocating tracheostomy in the second and third tracheal rings rather than a high tracheostomy (cricothyrotomy).

Anatomy:

An article issued on palliative care tracheostomy by Teresa Chan et al published in Otolaryngology Clinics of North America 42 (2009) 133 – 141 stated relevant anatomy knowledge as important in tracheostomy. People who perform tracheostomy should be familiar with the anatomy.

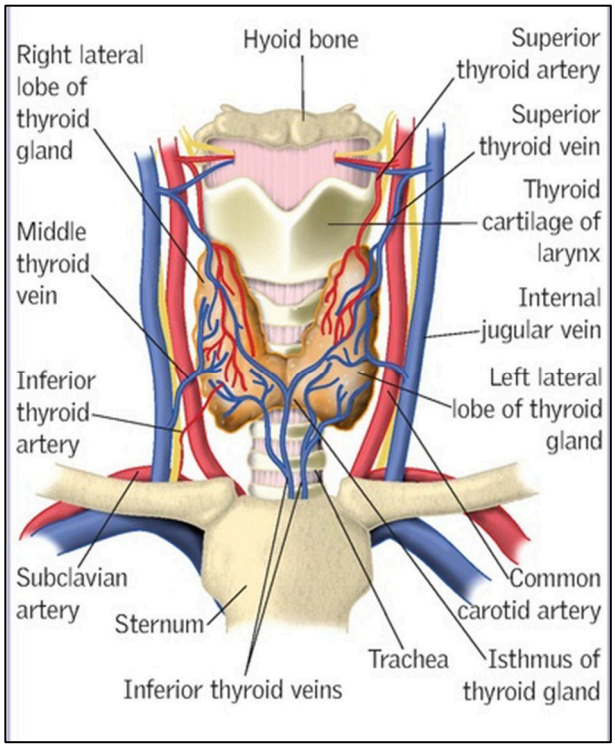


Figure 1:- Anterior Neck

The trachea should be palpated below the thyroid and cricoid cartilages in the midline of the neck. The sternal head, thyroid cartilage, and cricoid ring are all important markers to recognize which forms the Jackson triangle.

There can be less prominent landmarks in patients who have thick neck, neck malignancy, or serious infection. While placing Tracheostomy tube one can encounter with thyroid gland it is important to recognize below structures, because trachea may not be in midline in few patients due to diseases of lungs which may pull trachea to one side; some patients trachea may be deeper and away from neck skin.[26]

Physiology of the Larynx:

Larynx is classically designed to perform three main functions, in order of lowering gravity :(a) Breathing (b) Protections air pipe during swallowing(c) Vocalization. In addition fourth function which has been described as Valsalva maneuver which increase subglottic air pressure during exertions lifting weight or breathing against closed glottis.[27]

Supra-glottis, glottis and sub-glottis are the subdivisions of larynx. The bottom half of the laryngeal sinus, voice fold, paired pyramid shaped arytenoids, anterior and posterior commissures are all included in the glottis. Depending on insertions in the larynx, the laryngeal framework is split into extrinsic and intrinsic types. Adduction, abduction and tensing vocal cords, are done by intrinsic muscles whereas extrinsic muscles elevate larynx, moving it as a whole.[28] Posterior cricoarytenoid is the only abductor muscle. Motor supply to all intrinsic muscles is by recurrent laryngeal nerve, except for cricothyroid which is innervated by superior laryngeal nerve and which angles thyroid cartilage over cricoid, which is tensor of vocal cords.[29] Superior laryngeal nerves provide sensory innervation to supra-glottis and glottis, whereas recurrent laryngeal nerves provide sensory sensation to sub-glottis. Vocal chords open during breathing and rest in this position. During deglutition larynx ascents and vocal cords close instantly, which block glottic plane and prevent food particle entering air pipe [30] Myo-elastic and vibrating nature of vocal folds produces multi-laminated vibrator during vocalization, which produces sound. Finally sound wave are amplified in resonators of vocal tract at different levels [31].

Tracheostomy and Deglutition:

Tracheostomies curb the air flow through glottis, it lowers glottic sensations and curb increase of subglottic pressure during swallowing.[32,33]In addition inflated balloons of the portex (Fig 2) tube could revise the mechanism of swallowing.[34,35]

Figure 2 :- Portex Cuffed Tracheostomy Tube

Tracheal tube's balloon or cuff goal forms an air tight around tube and, exquisitely prevent secretions from passing through. Nonetheless, multiple studies demonstrate that the typically used high volume/low pressure balloons do not prevent aspiration, allowing fluids to flow through the folds that emerge when the balloon adjusts to the tracheal wall.[36-39]

Furthermore, tracheostomy cannula may inhibit elevation of larynx during deglutition [40], however recent research suggests that effect is lower consequential than originally thought.[41,42] Kang et al studied laryngeal kinematics of 13 patients

examined by video fluoroscopy before and after decannulation didn't find significant discrepancy during deglutition.[41]

Studies in comatose patients has shown tracheostomy would not depress swallowing. Therefore, existence of tracheostomy would not facilitate aspiration, nor prevent it from happening.[43,44] In a study conducted by Leder and Ross on 25 patients no significant differences was found when comparing presence of aspiration before and after doing tracheostomy. By way of explanation, those who had aspiration before tracheostomy kept it, whereas those who didn't had it before the tracheostomy didn't develop it later [43].

Operative procedure:

Tracheostomy can be performed by open and percutaneous technique. Open tracheostomy is done by palpating the skin and marking below the level of the cricoid cartilage roughly corresponding to second tracheal ring. Neck is extended using sand bag so that trachea comes anterior and incision site prepared in sterile fashion, it's important to know surface landmark for dissection to reduce complication dissection should be carried out within the Jackson triangle

A vertical incision is taken on skin and soft tissue is dissected with help of artery to reach trachea. Once strap muscles are seen they are divided of median raphe and pulled laterally. (Fig 3)

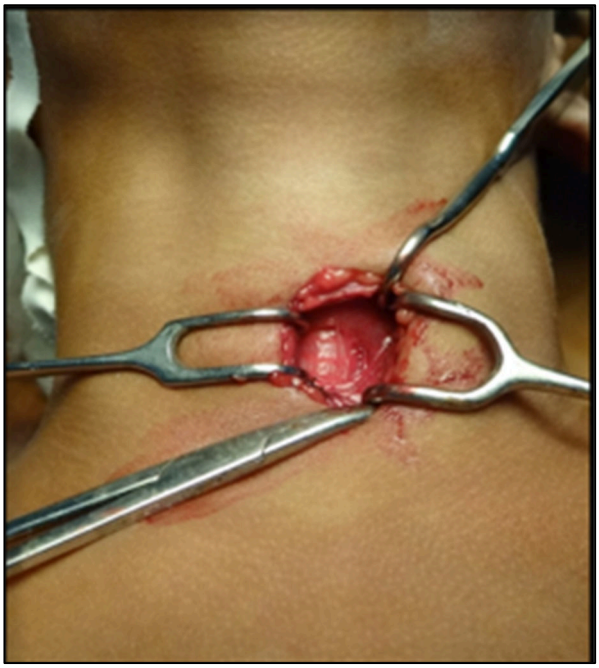


Figure 3:- Strap muscle Retracted

Thyroid isthmus is encountered and divided. (Fig 4)

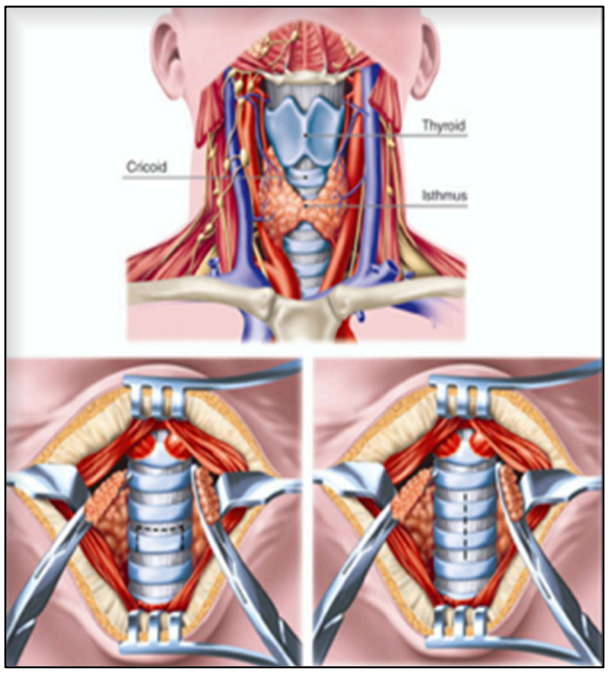


Figure 4:- Anterior Neck - Division of Thyroid Gland

Trachea is identified and confirmed by using syringe which demonstrate air bubble, a cruciate incision is take over the trachea between 2nd and 3rd tracheal rings and trachea is entered. (Fig :-5)

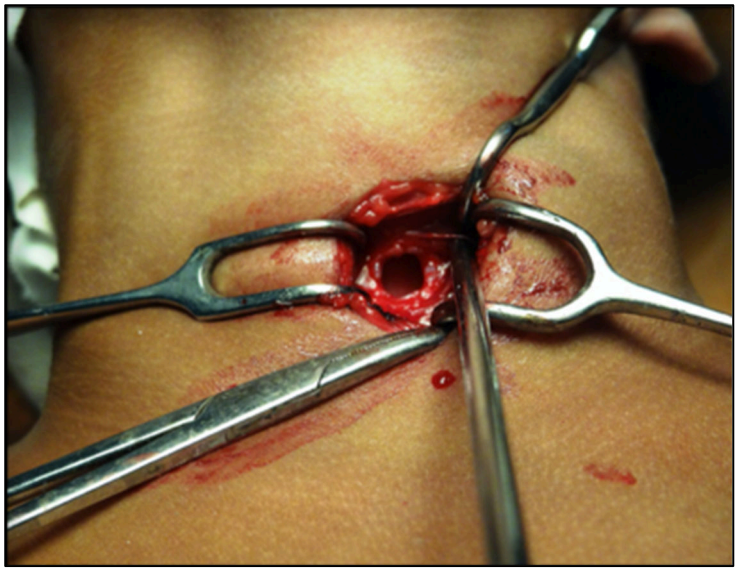


Figure 5:- Tracheal stroma creation

Once trachea is entered, final steps to put appropriately sized tracheostomy tube roughly based on endotracheal size and to secured it around the patient's neck and confirming it by auscultation. (Fig: - 6)

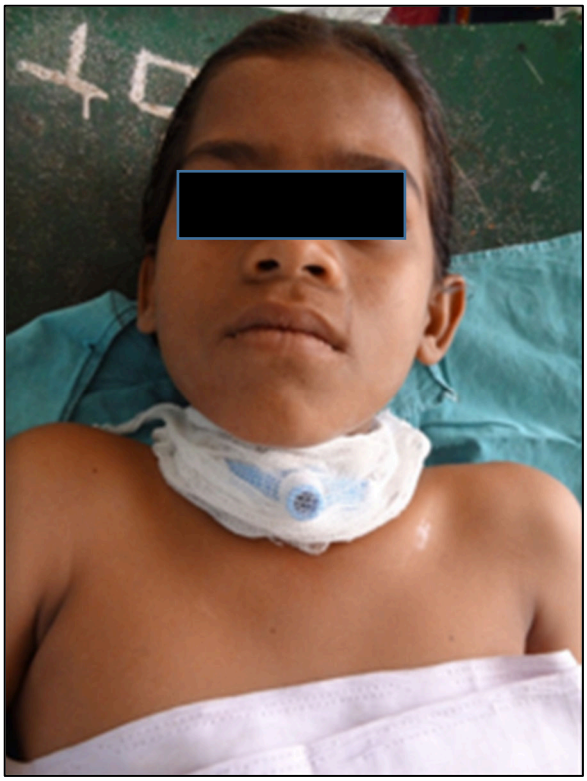


Figure 6:- Tracheostomy Tube In Position

Anatomic boundaries of percutaneous method is similar to open method. Trachea is entered by making a small anterior skin nick. Same time trachea-bronchoscopy is used to visualize percutaneous airway instrumentation. Tracheal interspace is entered using a needle. A wire is introduced through the needle into the airway, allowing percutaneous dilators to travel into the wind pipe. Wind pipe is therefore prepared for the insertion of a tracheostomy tube.

Effects of tracheostomy:

The patient breathes through the tracheostomy tube instead of breathing through the natural pathway.

In addition to its role of by passing the upper airway, its other functions include.

- Helps to reduce dead space in the lungs. The usual tidal capacity is around 500 ml, with roughly 200 ml of dead space. The nose, throat, and pharynx account for half of all dead space. Depending on the individual's physiological dead space, the reduction in dead space after tracheostomy might range from 10% to 50%. When respiratory function is hindered and tidal air is diminished, this seemingly insignificant amount of air becomes critical.
- Airflow resistance is minimized because it avoids an incapable voice box and pharynx, as well as the consequence of glottic constriction. As a result, the working load of respiration is lowered. If the tracheostomy stoma is large enough, this will improve lung compliance and promotes effective alveolar ventilation.
- In case of feeble laryngeal reflex cuffed tube protect the airway from aspiration.
- Respiratory disease patients it permits deglutition without reflex apnea.
- Permits removal of dried mucous and oral secretions. If not removed it increased capillary permeability, which leads to anoxia. With the suctioning of tracheostomy secretions through stroma and it promotes ventilation of the lungs.

- Provides pathway to deliver drugs and humidification of tracheobronchial system.
- Tracheostomy replaces the ineffective cough.
- Provides easy, hustle free, and positive avenue for administering artificial ventilation to patients with defective respiratory mechanisms, such as those with Poliomyelitis, paralyzed respiratory muscles, and others, until spontaneous breathing is restored.
- It can be used as a route for bronchoscopy and administering the anesthesia or removing foreign bodies. Bronchoscopy through this route is technically simpler, passage of instruments is easier.
- Provides a straightforward method for administering anesthetics. Light planes of anesthesia and a high flow of oxygen are maintained. Because the risks of aspiration are considerably minimized with a tracheostomy, the patient will wake up quickly and be able to feed virtually immediately. This procedure can be used for both initial and follow-up surgical management of patients with burns and craniofacial injuries, and can be used cold or hot, dry air impinges.

Indications of tracheostomy:

In an article on tracheostomy by Andres Alvo et al 2012 – 2013, tracheostomy indications can be branched into three main groups: A) Hindrance of upper airway B) Long term mechanical ventilation (MV) C) Aiding management of bronchopulmonary secretions[45]. Although aspiration is not commonly considered as explanation but, it can help with pulmonary washing in temporary and mild cases. Intractable aspiration necessitates the use of particular surgical techniques[46,47].

A. Hindrance of upper airway:

1. Infections

- ❖ Croup, acute epiglottitis, diphtheria
- ❖ Submandibular, quinsy, para-pharyngeal and retropharyngeal collection.

2. Trauma

- ❖ Blow to larynx or trachea
- ❖ Fractures of mandible or maxillofacial injuries
- ❖ Endoscopic trauma, especially in infants and children

3. Carcinomas

- ❖ Benign and malignant growth of larynx, pharynx, tongue and thyroid

4. Laryngeal foreign body

5. Edematous airway due to irritant fumes or allergy (angioneurotic or drug induced) post-radiotherapy

6. Bilateral abductor failure

7. Inherent abnormality

- ❖ Bilateral choanal atresia
- ❖ Laryngeal web, cysts, trachea-esophageal fistula

B. Retained secretions:

1. Inadequacy to cough

- ❖ Comatose condition e.g. head trauma, cerebro-vascular accidents, drug overdose
- ❖ Paralysis of respiratory muscles in cases of vertebral injuries, myasthenia gravis, polio, acute inflammatory polyneuropathy

- ❖ Spasm of respiratory muscles, lockjaw, convulsions in pregnency, strychnine poisoning.

2. Agonizing cough

- ❖ Chest trauma, frail chest, chest infections

3. Aspiration of pharyngeal secretions

- ❖ Acute anterior poliomyelitis, multiple neuritis, bilateral laryngeal paralysis.

C. Respiratory incompetency:

- ❖ Chronic lung disease, pleurisy, chronic bronchitis, bronchospasm, lung collapse.
- ❖ Conditions categorized in A and B.

Tracheostomy is not the cure for aspiration it can aggravate it by inhibiting elevation of larynx with swallowing. Schonhofer and colleagues[48] documented aspiration in thirty percent tracheostomized patients. Drug used to control excessive secretions, food texture, speech language pathologist bracing of swallowing methods, and adoption of nonoral feeding choices are all first-line treatments for preventing aspiration (eg, parenteral nutrition and nasogastric tube feeds).

If medical approaches has failed to find indecisive for durable solution, tracheostomy should be considered. Surgical intervention may be acceptable in the palliative care environment for incurable lethal aspiration and to improve patient comfort.

A study in 2008 by Allam Choudhary et al [49], intra-cranial space occupying lesion (ICSOL) (26.67 percent), head trauma (26.6 percent) was most common reasons for elective tracheostomy; other reasons included were mandible neoplasm Guillain-Barre Syndrome, stroke, and so on. Laryngeal cancer was the most common reason for an emergency tracheostomy (53.33 percent). Advanced hypopharyngeal

carcinoma was next (13.33 percent), and these indicators were identified in 47 percent and 12 percent of cases, respectively, in another investigation.

In a study by Santosh U.P et al [50](2011), During the course of the trial, a total of a hundred patients had a bedside tracheostomy while on mechanical ventilation. Polytrauma, brain death, poisoning, suicide, stroke, organ failure with septicemia, viral encephalitis, ARDS in respiratory distress were all reasons for mechanical ventilation in the individuals listed above.

A study in 2013 by A.M Kodiya et al [51], total of 111 cases were retrieved, Head and neck tumor were the most common reason for tracheostomy, accounting for 37.8%, secondly due to wind pipe foreign body (22.5 percent). Only 34 (30.6 percent) of the 111 tracheostomies were elective, with the rest (69.4%) being done as an emergency.

Contraindications:

Contraindication for tracheostomy or other intervention is patient refusal. Patient disapproval for giving consent without insight of procedure should be logic to cease and look for other alternatives. Preservation of patient autonomy is a key precept lectured from the beginning of medical journey, it can be disturbing for a surgeon when decision of patient differ what would be considered medically "the best alternative." patient's freedom to choose in palliative care, as in all health institutions, must be honored and preserved. Prior to cognitive decline, advanced forward directives and a proxy decision maker should be established. This is current standard of care. We should keep in mind in critically ill patients who have lost their decision-making competence prior to hospitalization the power should be given in the hands of relative for resuscitation and best care as stated in the SUPPORT study. [52]

Anatomic or patient condition that limit safe, successful outcome of the procedure with acceptable blood loss are also relative contraindications to tracheostomy. For example, extensive thyroid tumor prevents safe surgical door to airway, it's best that patient stay intubated rather to undergo tracheostomy. Situation in hindrance far from trachea for which patient is chronically intubated (eg, bronchus lymphoma), tracheostomy would be waste in maintaining airway. If patient's religious culture forbids use of adjuncts that may be required for safe surgery, surgical intervention should be approached with caution. Concerns about anesthesia, pulmonary function, cardiac output, and torrential bleeding in case of blood disorder, must be expressed against the benefits of surgery.

Complications:

The complications of tracheostomy fall into the following categories:

- IMMEDIATE:
    - Anesthetic obstacle
    - Haemorrahge
        - Inferior thyroid veins
        - Anterior and external jugular veins
        - Arteries
    - Air embolism
    - Apnea
    - Cardiac failure
    - Injury to airway
- INTERMEDIATE:
    - Deracination of the tube
    - Surgical emphysema

- Pneumothorax / pneumomediastinum
- Infection: Perichondritis
- Tube block by secretions or crusts
- Tracheal ring necrosis
- Tracheo-arterial fistula
- Tracheo-esophageal fistula
- Dysphagia

- LONG TERM
  - Stenosis
  - Granulation formation
  - Decannulation trouble
  - Tracheocutaneous fistula
  - Disfiguring scar

A study by Arola et al [53] (1981), 794 tracheostomized patients were include in study to lay down complication related with tracheostomy. Bacterial growth was seen in ninety-two % of patients from whom tracheal secretions were taken, crusted airways in five %, 16% showed trachea-bronchitis, pneumonia in 22% and trachea-bronchial haemorrhage in 22% Five of them had tracheo-arterial erosion with significant bleeding, with just one example of treatment being successful. At autopsy, three victims were found to have a tracheo-esophageal fistula. Nine patients developed tracheal stenosis after being extubated, and two died. Overall fatality rate was 46%, indicating the severity of the patients' illnesses. The death rate associated with tracheostomies was 1.4 percent.

A paratracheal mediastinal abscess has been reported post-operatively but is rare.[54] Tracheitis infection of the tracheal mucosa result if the trachea is allowed to dry out and which may lead to perichondritis and subsequent tracheal stenosis. To prevent complication adequate humidification and correctly fitting tubes are essential.

In a study by Goldenberg et al [55] (2000), there were 1130 tracheotomies performed. In 49 of the instances, major problems developed, and 8 loss of life were directly linked to tracheotomy. Tracheal stenosis was most prevalent consequence, occurring in 21 instances. Following which complication was haemorrhage, developed in 9 cases.

Above study was largest meta analyses ever compiled which demonstrated relatively low overall complication and mortality rate compared with other study. In contrast to other study, tracheal stenosis was most frequent problem. This could be the result of tracheal injury induced by extended intubation prior to the tracheotomy. All tracheotomy issues can be avoided or reduced with proper surgical technique and subsequent care.

Ironically the associated infection of trachea is not mentioned and documented as complication and requires further study.

MATERIALS AND METHODS

- **Study period:** January 2020 to December 2021
- **Sample size:** As in study conducted by Mukundan A et al [5]
- P= 86.9%. q =13.1%
- d = 15% of p =15/100*86.9= 13.035
- Using the formula $n = 4pq/d^2 = 4*86.9*13.1/ (13.03)^2 = 26.8\sim 27 *1.1$(attrition) =29.7 ~30
- So, the number of patients required is 30
    - Includes all the patients in Intensive care unit in the given period of time who satisfy the inclusion criteria and do not come under the exclusion criteria
- **Inclusion criteria:**
    - Patient undergoing tracheostomy in KLES Dr. Prabhakar Kore Hospital.
- **Exclusion criteria:**
    - Patient admitted for a known infective condition of chest and who underwent tracheostomy
    - Patients diagnosed with community acquired pneumonia or tuberculosis
    - Patient who developed lung infection during their stay at hospital and subsequently underwent tracheostomy.

- **Methodology:**

- After obtaining clearance and approval from institutional ethics committee and written informed consent from patient attender in those patients who fulfill the inclusion criteria will be enrolled in the study.

- Demographic data, detailed history of chief complaints and other relevant history will be recorded. Later the examination of the patient is done and all the findings will be recorded in study proforma.

- Tracheostomy will be performed either under local anesthesia or general anesthesia. After painting and draping surgical area infiltration will be given in Jackson triangle (Photograph 2) with 2 percent lignocaine and 1 in 1,00,000 epinephrin. Tracheostomy set opened (Photograph 1) a horizontal or vertical incision will be given two finger breadths above suprasternal notch (Photograph 3) Subcutaneous tissue and platysma will be incised horizontally and the strap muscles will be retracted laterally. Isthmus of the thyroid gland if encountered will be retracted superiorly and tracheal rings will be identified. Pre tracheal fascia will be cleared off the anterior surface of the trachea. Position will be confirmed by aspirating air from trachea with saline filled syringe and 4% lignocaine will be injected into lumen to anaesthetize tracheobronchial tree mucous membrane (Photograph 4). Trachea will be incised at the second or third tracheal ring on anterior wall of the trachea. Cuffed tracheostomy tube will be introduced and position will be confirmed. Tracheal suctioning will be done to clear secretions form tracheobronchial tree. Tube will be secured with tapes and wound closed with sutures.

- A total of three samples of tracheal aspirate will be collected using a sterile suction tip catheter from each patient for the study.
- 1st sample – during tracheostomy
- 2nd sample – 5th day of tracheostomy
- 3rd sample – 10th day of tracheostomy
- For the collection of samples, (Photograph 5) sterile suction catheter will be introduced into trachea and suctioning will be done to clear secretions. Under aseptic precaution tip of suction catheter will be cut and placed in sterile container and will be sent for bacterial culture for bacteriological analysis.
- Cultural results will be followed up and noted down.

The data will be analyzed using appropriate statistical tools. Descriptive statistical analysis will be carried out in present study. Results on continuous measurements are presented on Mean ± SD and results on categorical measurements are presented in Number (%). Chi-square/ Fisher Exact test will be used to find significance of study parameters on categorical scale between two or more groups. P value <0.05 will be considered statistically significant.

Ethical clearance for the study was obtained from JNMC Institutional Ethical Committee on Human Research and the reference number was **MDC/DOME/303**

Patient undergoing tracheostomy in Intensive care unit in KLES Dr. Prabhakar Kore Hospital during the study period.

Patients depending on indications tracheostomy done on both elective and emergency basis.

Preoperative and postoperative patients were subjected to blood examination, X-ray lateral view neck, PA view chest

Post- operative care

- Tracheostomy care Post-operatively was given by the surgeon and the stationed nurse, attenders were asked to observe the procedure. Tracheostomy care was given once in the morning and again in the evening. If patient was to be discharged with tracheostomy tube in-situ, then the Portex tube was changed to Jackson's tube (Photograh 6) or Fuller Bi -flanged tube (Photograph 7) Regular follow was done.
- Two times in a week – 1 st mnth
- One time in a week – 2 nd mnth
- Finally patients were asked to come in case of any problem. During follow up patients were taken to Minor OT, inspection of tracheostomy tube, cleaning and dressing was done. Progress was stated.
- When tracheostomy was no longer required tube was downsized and blocked, after confirm adequacy of laryngeal airway, cough reflex effective swallowing, sensorium of the patient the tube was decannulated (Photo 8) and an air tight dressing applied.

OBSERVATION AND RESULTS

Table 1: Age wise distribution of patients

Age groups	No of patients	Percentage of patients %
18-30yrs	11	36.67
31-40yrs	3	10.00
41-50yrs	4	13.33
51-60yrs	7	23.33
61-80yrs	5	16.67
Total	30	100.00
Mean	41.97	
SD	16.87	

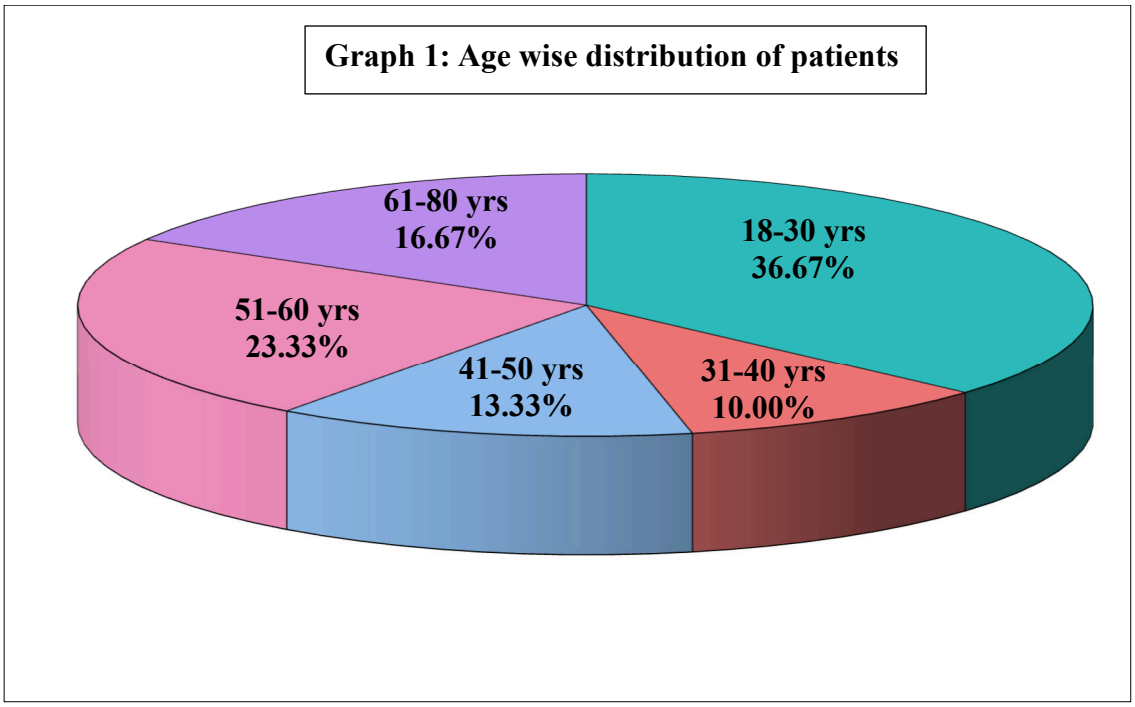


Table 2: Gender wise distribution of patients

Gender	No of patients	Percentage of patients %
Male	23	76.67
Female	7	23.33
Total	30	100.00

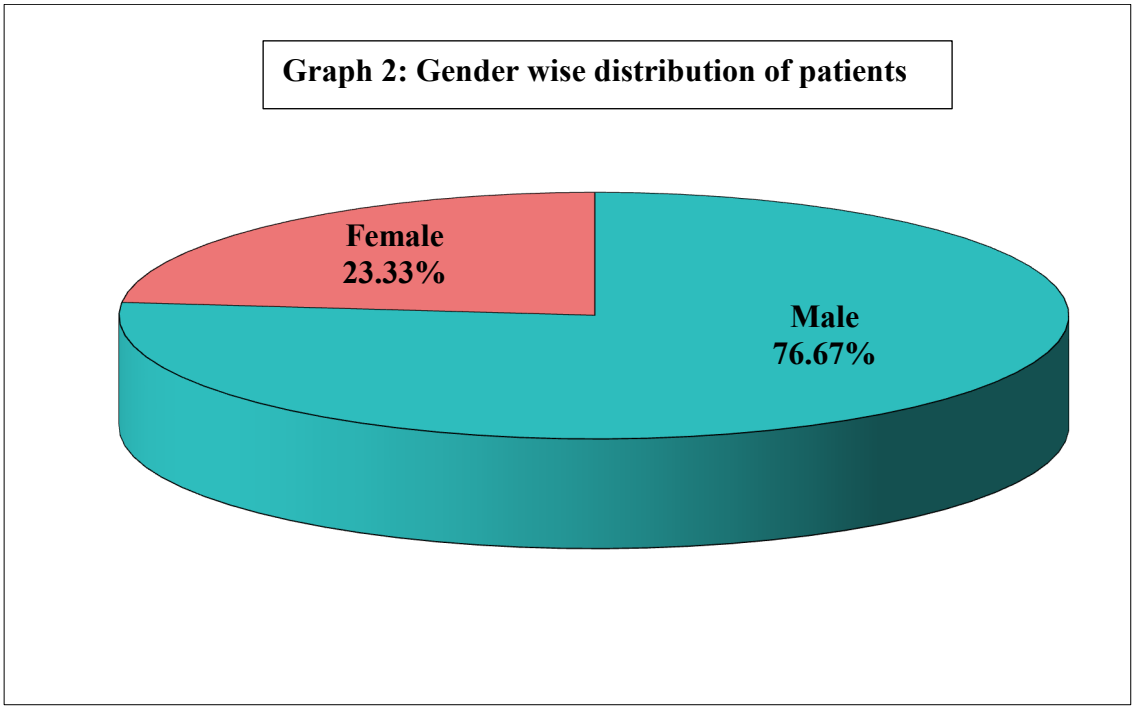


Table 3: Type of anesthesia wise distribution of patients

Type of anesthesia	No of patients	Percentage of patients %
General anesthesia	13	43.33
Local anesthesia	17	56.67
Total	30	100.00

Graph 3: Type of anesthesia wise distribution of patients

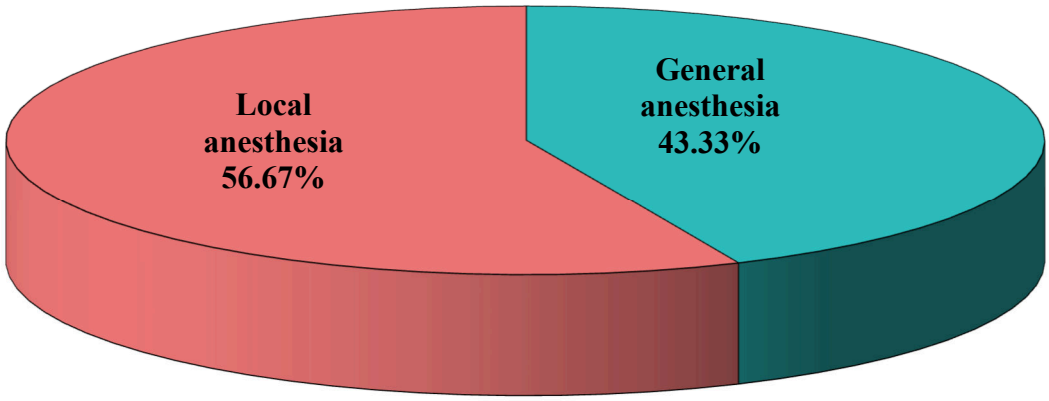


Table 4: Different organisms present at day -0-(zero)

Day 0	Number	Percentage%
Coagulase -ve staphy sp.	1	3.33
E coil	1	3.33
Enterococcus casseliflavus	1	3.33
K pneumonia	11	36.67
Klebsella oxytoca	1	3.33
P aeruginosa	3	10.00
Serratia marcescense	1	3.33
St epidermis	2	6.67
Streptococcus Pyogene	1	3.33
No organism	8	26.63
Total	30	100.00

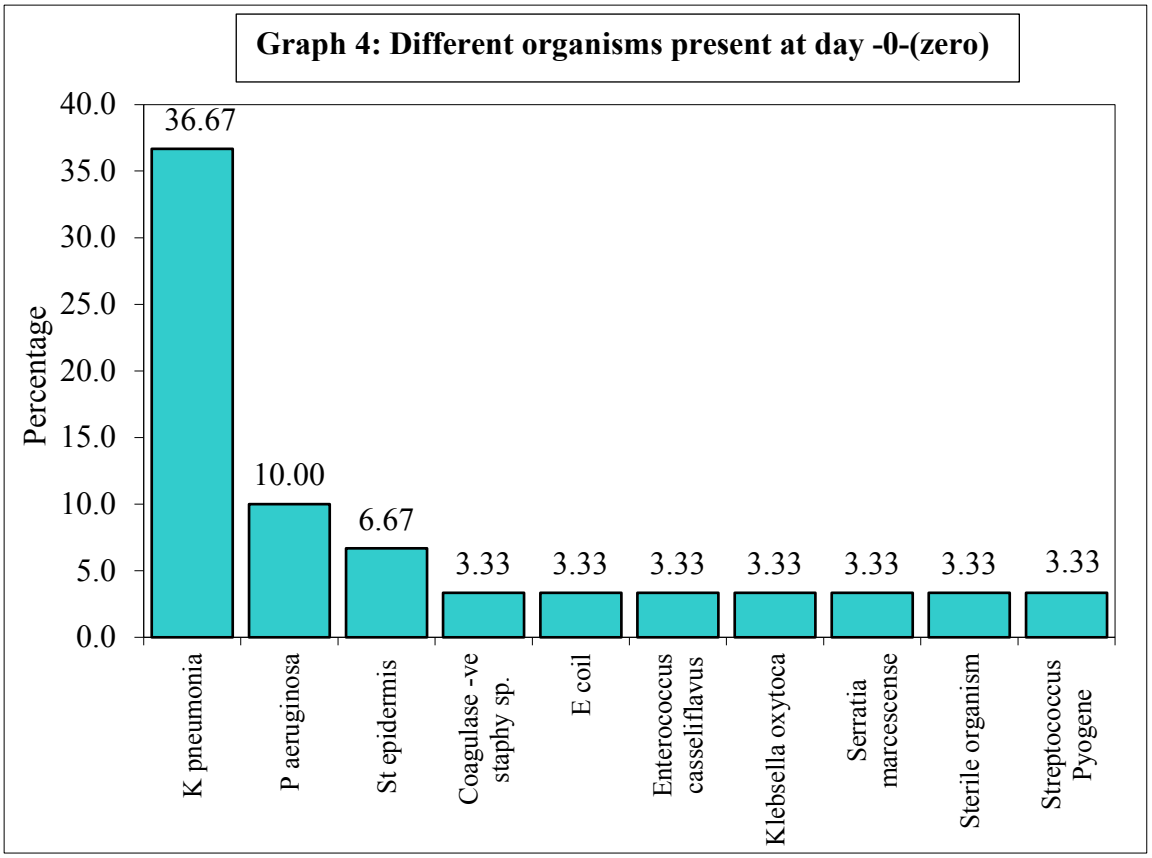


Table 5: Different organisms present at day- 5

Day 5	Number	Percentage%
Acinetobacter baumanii	2	6.67
Candida species	1	3.33
Citrobacter freunddi	1	3.33
Coagulase -ve staphy sp.	1	3.33
Enterobacter	1	3.33
Enterobacter clocae	2	6.67
Enterococcus	1	3.33
K pneumonia	12	40.00
P aeruginosa	6	20.00
Staphy Epidermis	1	3.33
No organism	2	6.67
Total	30	100.00

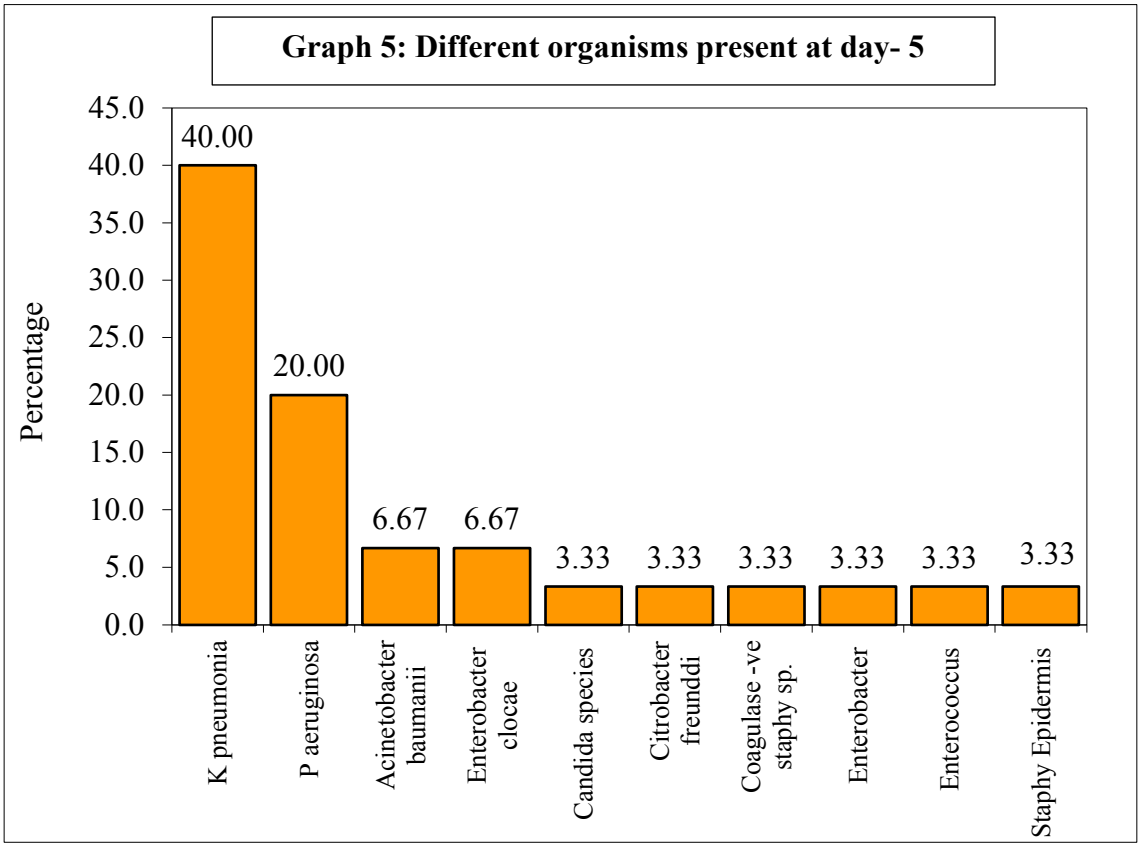


Table 6: Different organisms present at day -10

Day 10	Number	Percentage%
Acinetobacter baumanii	2	6.67
Burkholderia cepacia	1	3.33
citrobacter freunddi	1	3.33
E coli	2	6.67
Enterobacter clocae	1	3.33
Enterococcus faecalis	2	6.67
K pneumonia	6	20.00
P aeruginosa	12	40.00
St aureus	1	3.33
No organism	2	6.67
Total	30	100.00

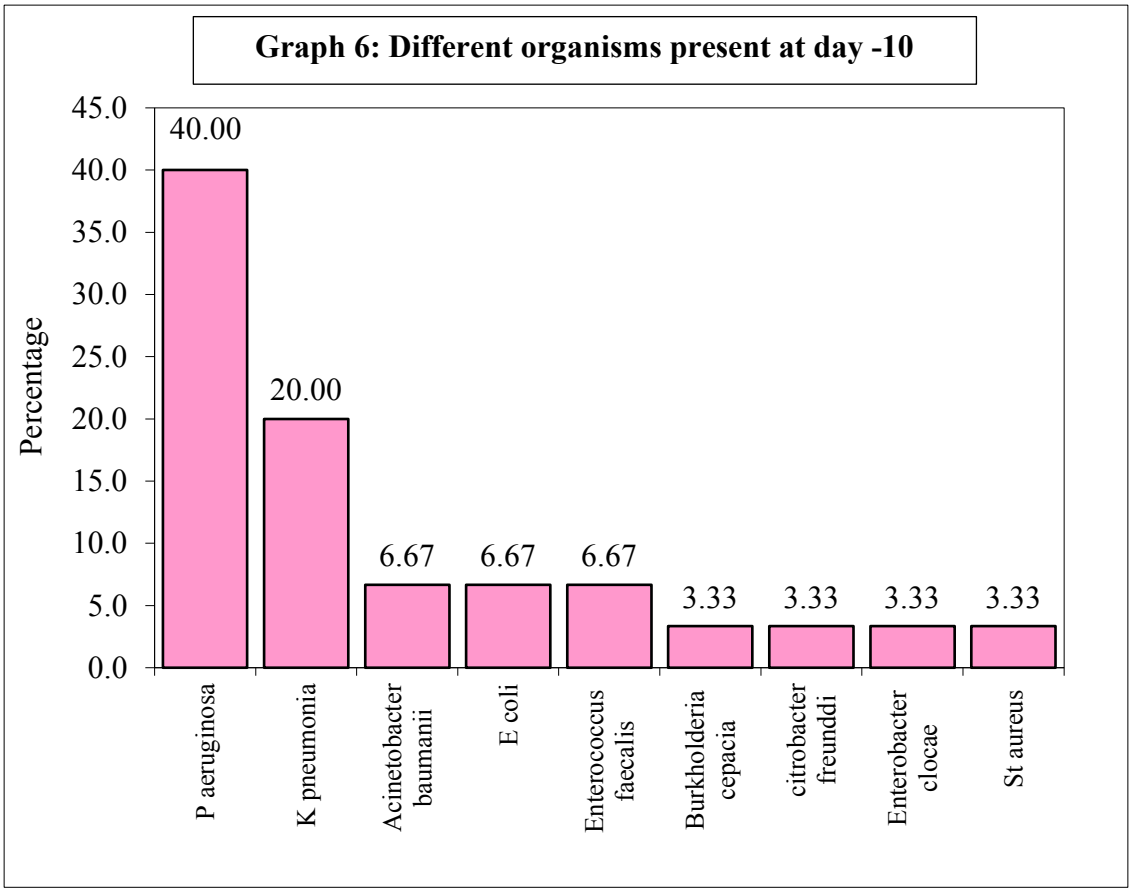
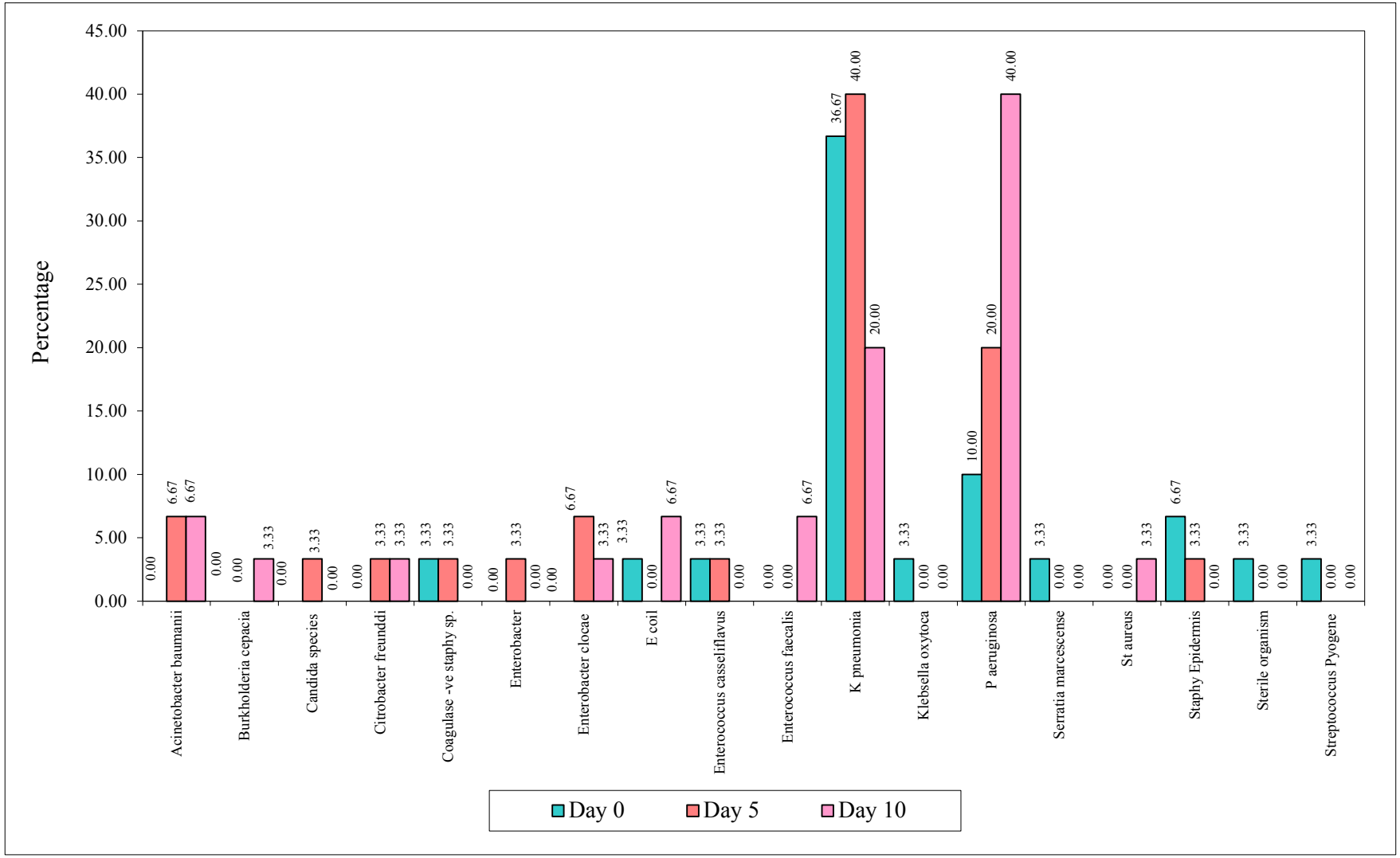


Table 7: Comparison of day 0, day 5 and day 10 with different organisms present

Organisms	Day 0		Day 5		Day 10	
	Number	Percentage%	Number	Percentage%	Number	Percentage%
Acinetobacter baumanii	0	0.00	2	6.67	2	6.67
Burkholderia cepacia	0	0.00	0	0.00	1	3.33
Candida species	0	0.00	1	3.33	0	0.00
Citrobacter freunddi	0	0.00	1	3.33	1	3.33
Coagulase -ve staphy sp.	1	3.33	1	3.33	0	0.00
Enterobacter	0	0.00	1	3.33	0	0.00
Enterobacter clocae	0	0.00	2	6.67	1	3.33
E coil	1	3.33	0	0.00	2	6.67
Enterococcus casseliflavus	1	3.33	1	3.33	0	0.00
Enterococcus faecalis	0	0.00	0	0.00	2	6.67
K pneumonia	11	36.67	12	40.00	6	20.00
Klebsella oxytoca	1	3.33	0	0.00	0	0.00
P aeruginosa	3	10.00	6	20.00	12	40.00
Serratia marcescense	1	3.33	0	0.00	0	0.00
St aureus	0	0.00	0	0.00	1	3.33
Staphy Epidermis	2	6.67	1	3.33	0	0.00
Streptococcus Pyogene	1	3.33	0	0.00	0	0.00
No organism	8	26.63	2	6.67	2	6.67
Total	30	100.00	30	100.00	30	100.00

Graph 7: Ty Comparison of day 0, day 5 and day 10 with different organisms present



DISCUSSION

The study was done in I.C.U and Department of Otolaryngology -Head and Neck Surgery in KLES Dr. Prabhakar Kore Hospital 30 cases of tracheostomies from January 2020 to December 2021

Age Distribution

This present study youngest to undergo tracheostomy is 18 and oldest 80. Maximum cases 11 performed between age group of 18-30 years (36.67%) 7 cases performed between 51-60 years (23.3%), 5 cases performed between 61-80 years (16.6%), 4 cases performed between 41-50 years (13.33%) ,3 cases performed between 31-40years (10.0%)

- A study in (2008) by Allum Choudary et al [49], elective tracheostomy mean age was 40 years and mean age of emergency Tracheostomy was 50 years. Prolong intubation with mean age for tracheostomy (41.9) was most frequent indication in present study.
- A study in (2011) by Santosh UP et al [50], total of hundred patients undergone bedside tracheostomy during course of mechanical ventilation. Earliest being eighteen years and oldest eighty -five years.
- A study in (2013) by A.M. Kodiya et al in Nigeria [51] showed M:F ratio of 2.5:1, 79 (71.2%) being males and 32 (28.8%) female among 111 cases.

SEX DISTRIBUTION

This present study 23 are males and 7 females out of 30 cases.

Authors	Ratio between males and females
Amusa et al – 2013	3 : 1
Eziyi et al – 2011	2.8 : 1
Okafor et al – 1981	1.4 : 1
Erkan Esen et al – 2012	2.3 : 1
Present Study	3.2: 1

A study in 1976- 1985 done by Crysdale [56] revealed higher incidence of male tracheostomy than females.

A study in (2011) by Santosh U.P et al [50] seventy-eight patients were male and twenty-two were female in ratio of 3.5:1 out of 100 patients who underwent bedside tracheostomy.

Type of Anesthesia:

Elective and emergency tracheostomies were done. Elective tracheostomies under general anesthesia in OT and Emergency tracheostomy was performed bedside under local anesthesia. In this study 17 cases were done under local and 13 cases under general anesthesia.

BACTERIAL GROWTH IN ASPIRATES

Trachea is considered sterile and free from micro-organisms in healthy individuals it shows resistance to bacterial colonization. Tracheostomy disables upper airway filtering systems, lowers the efficiency of the cough reflex, and prevents

glottic closure to the point that aspiration occurs often, all of which may contribute to bacterial colonization in these individuals in the future. The tracheal flora in patients with tracheostomies was evaluated qualitatively in this study. The lower respiratory tract is sterile, as demonstrated in the Day -0- culture, providing negative growth in 26.6 percent of cases in our study.

Only Klebsiella pneumoniae and P aeruginosa growth was observed in individuals who had previously been intubated and had a tracheostomy. Due to their terrible conditions, these patients spent the most of their time in intensive care unit (ICU). Thus, it's note-worthy that external intervention (endotracheal intubation) into the airways of these patients may have led to bacterial colonization. Most of these patient's showed persistent colonization with these organisms even after a week of tracheostomy and even after being on higher antibiotics like Carbapenems. Acenitobacter spps and Klebsiella pneumoniae are considered as hospital acquired. Endotracheal intubation increases the risk of infection by exerting direct effects on the airways, decreasing local host defences, diminishing muco-ciliary function, inducing mucus stagnation, and increasing bacterial entry, all of which contribute to colonization by these hospital acquired bacteria this finding implies that, even following thorough aseptic procedures, constant exposure to the organisms prevalent in the ICU, results in exogenous acquisition and colonization of the airways. It's also worth noting that the fact that most of these patients were on stronger antibiotics may have resulted in the development of multi-resistant bacteria, which could explain why colonization was so persistent. Despite the adoption of strict aseptic measures, the presence of germs in the hospital environment is unavoidable, resulting in persistent infection. The findings of this new study add to the growing body of data that airway colonization with potentially harmful microbes occurs following a tracheostomy.

After tracheostomy, the colonization of the patient's lower airways was found to be significantly higher than before the tracheostomy. Gram Negative Bacteria (GNB) were cultivated more frequently in the samples examined in our study. The most commonly isolated bacteria is Pseudomonas aeruginosa. Gram Negative Bacteria are most common pathogens causing nosocomial pneumonia, according to several other studies on tracheostomy.

A study done by Pignatti et al[57] microbiological study done on tracheal aspirates, Pseudomonas aeruginosa was seen in majority.

Bhat VK et al[58] noted heightened growth in gram-negative bacterial infection predominantly by pseudomonas in minor age group who underwent tracheostomy.

In a study conducted by Abdollahi et al [59] on intubated tracheostomized patients found a prevalence of gram-negative organisms, however unlike our findings, the bulk of the growth was of K Pneumonia (36 %), followed by Pseudomonas aeruginosa (40 %). Although the presence of a tracheostomy would have compromised nasopharyngeal defensive systems, allowing external bacteria direct access to respiratory airway, the higher prevalence of GNB in tracheobronchial flora was unexpected.

This finding suggests typical method of airway colonization, aspiration of pathogenic GNB from oropharynx (endogenous pathway), was not the cause of colonization in these cases. Rather, we believe GNB may have entered the trachea and attached itself to it (exogenous route). Tracheostomy care was given in ICU which may have directly lead to exogenous infection. One significant pathway identified for infection acquisition post-tracheostomy in patients who were not intubated prior to

tracheostomy is exogenous route, which is straight into trachea via the endotracheal tube or via tracheotomy stoma.

There are a lot of factors in play in a hospital environment which may contribute to similar situation. Pseudomonas aeruginosa is an opportunistic pathogen but once colonization is established, very difficult to eradicate.

Previous classic literatures especially the pioneering work done on the subject by Pseudomonas spp. can adhere to tracheal cells more vigorously, according to Niederman [60]. It's also likely that mechanical injury to trachea (from endotracheal intubation, tracheostomy tubes, or suctioning) exposed 24 new Psuedomonas spps binding sites. Another possible explanation being that the reparative changes which follows this injury allowed for enhanced binding of Pseudomonas aeruginosa. Unfortunately, all of the research on bacterial adhesion shows that the interaction is complicated, including numerous mucosal and bacterial features. As a result, interrupting this process with a single action is a difficult undertaking. Perhaps our awareness of micro-environmental factors that influence bacterial interactions will lead to fruitful prevention strategies. It may also be noted that most of these bacteria grown in our culture were just a colonization and did not progress towards a full-blown infection. All patients were on antibiotics prior to and after the procedure. Most commonly used antibiotic being third generation cephalosporin, Cefotaxime. In case of patients in the ICU, antibiotics were chosen by the primary physician.

Although we have not done antibiotic sensitivity in these samples, past research has led us to think that resistance to cephalosporins is likely in the majority of the bacteria examined.

Another study by Aliskan et al Gram-negative organisms, especially Pseudomonas aeruginosa and K Pneumonia has much more risk of multidrug-resistant pathogens.

Recent studies have also linked bacterial biofilms on tracheostomy tubes to persistent infection, which we believe is one of the primary causes of persistence colonization in this era of increased antibiotic prescriptions and stringent aseptic care, even if we have no evidence from our study.

We do recommend more specific studies are needed on this though. We as clinicians are thus faced with the most difficult question, whether to start antibiotics prophylactically to prevent infection or to treat infection once it establishes. Either way there are problems and it is indeed a topic of debate even now. Prophylaxis against infection is not suggested, according to us, since it will just help bacteria develop antibiotic resistance, making it more difficult to treat patients if they become sick. Instead, therapy should be based only on tracheal aspirate culture and sensitivity report. So, based on what we've learned from our research, to study the bacteria, note the development of drug resistance early, so that appropriate treatment can be started as soon as possible thus reducing patient morbidity and mortality. Repeated cultures of bacteria during the course of the treatment thus started would allow for the adjustment of therapy according to changes in flora or antibiotic sensitivity. The same is true for intubated patients who require routine endotracheal cultures since the lower airways will be colonized even before a tracheostomy is performed. GNB bacteria, we believe, would have played a significant role in lower airway infection in these individuals.

In a study done by Cendrero et al[61] on patients receiving mechanical ventilation, it was noted that most of patients who were previously intubated and who were on prior antibiotics showed a positive heavy growth of K Pneumonia and Pseudomonas aeruginosa in tracheal aspirate. In a recent research by Craven et al on 180 patients on mechanical ventilation, 22 percent of the patients' airways became extensively colonized with a bacterial pathogen, with multidrug-resistant pathogens identified in 39 percent of the patients. Presence of a tracheostomy, when combined with severity of disease prevalent in those who require this procedure, presents a risky condition that can lead to infectious complications and even patient death.

Although compelling evidence from our study and others may persuade clinicians to pursue evidence-based therapy, we strongly advise against it and underline the need of tracheal aspirate culture. Despite our doubts about the role of various host features in affecting the type of bacteria studied, our findings convinced us that host factors have a little role in colonization. We propose further studies on these in the future. We acknowledge the limitations of the study, as well as the likelihood that other confounding factors influenced the final results. To completely appreciate the duration of colonization and the number of individuals that develop a symptomatic infection following colonization, long-term research is required.

CONCLUSION

Colonization of tracheostomy site after the procedure is very swift to occur and monitoring of these patients with regular tracheal aspirate culture is the most important investigation to identify it. Patients with tracheostomy are at greater risk for acquiring respiratory tract infections which is largely due to Gram negative bacteria like Pseudomonas aeruginosa, Klebsiella pneumonia and Acenitobacter spps. Factors responsible for colonization are many, but most important as doctor's is to look for this emergence at early stage and to treat accordingly. This is most important than ever in this era of multi resistant strains of bacteria. The observation and study of the varying pattern of the organisms will definitely prove fruitful in treatment of infections of lower respiratory tract and tracheostomy stoma under our clinical settings. This present study most of the cases did not harbour organism immediately after the procedure but as the day of tracheostomy increases there was increased growth of Gram negative bacteria like Pseudomonas aeruginosa, Klebsiella pneumonia and Acenitobacter spps. Surveillance cultures from these sites, on the other hand, are critical in patients with infections such as tracheobronchitis, pneumonia, and tracheostomy stoma infection. As thus, we feel that a study with a bigger study population and a longer study duration should be conducted to strengthen and to enlight the findings of the current study.

SUMMARY

The present study entitled "**BACTERIAL FLORA OF THE RESPIRATORY TRACT FOLLOWING TRACHEOSTOMY IN INTENSIVE CARE UNIT PATIENTS: A ONE YEAR PROSPECTIVE STUDY IN PRABHAKAR KORE HOSPITAL"** was conducted in the Department of Otorhinolaryngology and Head and Neck Surgery of KLE University's Jawaharlal Nehru Medical College and KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Belgaum from January 2020 to December 2021. The study included 30 patients who underwent tracheostomy for various indications. The tracheal aspirates and tracheostomy stoma site specimens were collected in these patients on days 0, 5, and day 10 post tracheostomy. The microbiological patterns of these specimens were studied.

- The most common age group was between18-30 years (36.67%) and between 51 to 60 years (23%).
- On day 0, 26% of patients showed no growth in tracheal aspirate as compared to 93% on day 5 following tracheostomy.
- On day 0, 36% of patients showed K pneumonia tracheal stoma as compared to (40%) on day 5 following tracheostomy.
- 3 (10%) patients showed P aeruginosa growth on day 0 of aspirate as compared to 6 (20%) patients on day 5 and 20 (12%) on day 10 post tracheostomy.
- No growth of St aureus was noted on days 0, 5 with 1 (3.3%) on day 10.
- 73.4% of patients showed polymicrobial growth on day 0 in stoma as compared to 93.4% patients on day 10 post tracheostomy.
- The most common organism isolated in day 0 and day 5 aspirate was K pneumonie which was present in 36% and 40% of isolates respectively.

- The isolation of Aerobic Gram-Negative bacteria (AGNB) increased from 21 (75%) on day 1 to 25 (86%) on day 10 of the aspirate.
- The most common organism isolated from stoma on day 0 was K pneumonie which constituted 11 (36%) of the isolates whereas on day 10 the most common organism isolated was *Pseudomonas aeruginosa* which was 12 (40%). Hence there was a shift in the growth from gram-positive cocci towards gram-negative bacilli (GNB)
- Though results showed increase frequency of growth from tracheal aspirate and tracheostomy stoma but the stroma site remain healthy in all patients.

  •Anaerobes isolated from aspirate and stoma were negligible, including Bacteroides fragilis, Peptostreptococcus assacharolyticus, Prevotella species, Bilophila species, and Peptococcus among the organisms isolated.

Tracheostomies are being performed more frequently in ICUs as a palliative care procedure to give patent airway, it makes suctioning easy, provide good oral care, and decreases patient morbidity. It also reduces the damage to the vocal cords that endotracheal tubes cause. Performing a tracheostomy reduces the amount of time spent on mechanical ventilation and in the ICU, as well as the number of antibiotics and sedatives required. Elective and emergency tracheostomy were performed elective tracheostomy (80%) was more common than emergency tracheostomy (20%). Tracheostomy safely is assured under Local anesthesia

In emergencies, incision taken is vertical. It has distinct benefit of speed, access, and spontaneous wound drainage, but the scar is the sole drawback. It's a small price to pay for such a wonderful life.

Three cases of granulation tissue formation at the tracheostomy site, five cases of tube obstruction, two cases of haemorrhage, three cases of surgical emphysema, three cases of stoma infection, one case of difficult decannulation, and one case of tracheal constriction were among the outcomes (3 cases). There were no deaths as a result of the tracheostomy.

Emergency tracheostomies are three times more likely than elective tracheostomies to cause difficulties. A tracheostomy carries little danger of death. First 24 hours are crucial in the management of tracheostomized patients, patient may have tubal block due to secretion and retained blood clots in tube and airway, which should be monitored and frequently suctioned and cleaning of tube, controlling bleeding and preventing aspiration.

- Minimal intra-operative and immediate post-operative complications can be achieved with detailed anatomical knowledge about trachea and surrounding structures, surgeon skill, aseptic technique, meticulous surgery, cuffed portex tubes, good bedside tracheostomy care.

- Majority of these dangers can be avoided with adequate skill and postoperative care but one should not forget that Tracheostomy is life-saving surgical procedure which carries some risk.

- We feel that while doing tracheostomy, whether be elective or emergency, a thorough and proper method should be adopted, based on the findings of our study and the literature review. Most significantly, all junior ORL residents must be trained in tracheostomy to deal with any future situations.

The classical surgical tracheostomy procedure is being utilized today as a life-saving treatment. It is especially true with the developments in healthcare facilities and the addition of l ICU equipment such as ventilators, which need tracheostomy at the time of management. As a result, all ORL residents must be trained to execute tracheostomy precisely without supervision. With a cautious approach and proper post-operative management, complications can be minimized

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ANNEXURE I. ETHICAL CLEARANCE.

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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Ref: MDC/DOME/303 **Date: 24/12/2019**

To.

BE0119001

PG student in Otorhinolaryngology and Head & Neck Surgery,
J. N. Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"BACTERIAL FLORA OF THE RESPIRATORY TRACT FOLLOWING TRACHEOSTOMY IN INTENSIVE CARE UNIT PATIENTS: A ONE YEAR PROSPECTIVE STUDY IN PRABHAKAR KORE HOSPITAL"**, is ethical and justifiable.

The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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

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

ANNEXURE II

INFORMED CONSENT

"BACTERIAL FLORA OF THE RESPIRATORY TRACT FOLLOWING TRACHEOSTOMY IN INTENSIVE CARE UNIT PATIENTS: A ONE YEAR PROSPECTIVE STUDY IN PRABHAKAR KORE HOSPITAL"

PRINCIPAL INVESTIGATOR:

CO-INVESTIGATOR :

INTRODUCTION AND PURPOSE

The present study is conducted among patients in intensive care unit in KLE's Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum and will be investigated for bacterial flora of respiratory tract following tracheostomy. You are requested to participate in the study and your participation is completely voluntary.

PROCEDURE:

If you agree to participate in this study, the relevant data will be collected as per the proforma .After getting inducted in the study, you will be evaluated for bacterial growth following tracheostomy and sample will be collected at day 0, 05, 10

BENEFITS:

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

RISKS:

Methods applied to do the study are safe.

COST OF PARTICIPATION:

The cost of the Investigation will be borne by the Study Subject. The other indirect expenses will be borne by the Investigator.

THE RESULTS OF THE STUDY MAY BE PUBLISHED

PRIVACY AND CONFIDENTIALITY: In Journals for Scientific Purposes. However, your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY:

You can withdraw from the study at any time if you wish to do so.

AUTHORIZATION TO PUBLISH THE RESULTS:

The researcher may use the information gathered from this study for presentation in scientific meetings. However, your identity will not be revealed.

QUERIES AND CONTACT:

If you have any queries regarding the study, without any hesitation on. If you have any questions about rights as a research participant, Jawaharlal Nehru Medical College Institutional Ethics Committee on human subjects' research.

CONSENT SUMMARY:

I have been explained all the contents of this consent form in my local language and having understood and clarified all my queries about the study to the best of my knowledge, I hereby give my voluntary consent for participation in the study. I do sign the informed consent form in front of an eyewitness whom I recognize.

DETAILS OF THE STANDARD PROCEDURE

All the 30 cases have undergone standard surgical tracheostomy procedure at bedside in ICU or emergency operation theater depending upon the indication.

The skin is palpated and marked below the level of the cricoid cartilage at the approximate level of the second tracheal ring. With the patient's neck extended using a shoulder roll and the skin prepared in a sterile fashion, a vertical incision is made long enough to facilitate access to the deeper tissues and trachea. Once the strap muscles are encountered, they are pulled laterally after division of the median raphe. The thyroid isthmus is encountered and divided. The trachea is identified, and the interspace between the second and third tracheal rings is located. This interspace is sharply incised, and the trachea is entered. Once the airway is entered, the final steps to creating a tract are at hand. After creating the opening and tract, an appropriately sized tracheostomy tube is placed within the opening and secured to the patient.

A cuffed portex tracheostomy tube was used in all cases, later the tube changed to Jacksons tracheostomy tube.

Once the need for a tracheostomy is over, the tube was removed. After the tube has been removed, the fistula was plugged with a small guaze square and the skin edges bought together in a butterfly fashion with elastoplast tape.

Name and Signature/ left thumb impression of the participant:

Name and Signature of the interviewer:

Name and Signature/ left thumb impression of the eyewitness (Relative):

Signature of the guide: **Date**

ANNEXURE III

PROFORMA

"BACTERIAL FLORA OF THE RESPIRATORY TRACT FOLLOWING TRACHEOSTOMY IN INTENSIVE CARE UNIT PATIENTS: A ONE YEAR PROSPECTIVE STUDY IN PRABHAKAR KORE HOSPITAL"

Name:

Opd / IP no:

Date of assessment:

Age:

Date of discharge:

Diagnosis:

Sex:

Address:

Phone no:

CLINICAL PROFILE:

Chief Complaint:

History of Present Illness

Past History:

Personal History:

Family History:

I) GENERAL PHYSICAL EXAMINATION -

Blood Pressure:

Pulse:

Respiratory Rate:

Pallor

Icterus

Clubbing

Cyanosis

Lymphadenopathy

Oedema

II) ENT Examination

1. EAR EXAMINATION:

	Right	Left
Pinna		
Pre auricular area		
Post auricular area		
External auditory canal		
Tympanic membrane		

TUNING FORK TESTS:

Rinne's test	256 Hz	
	512 Hz	
	1024 Hz	

Weber's test:

Absolute Bone Conduction test:

FACIAL NERVE EXAMINATION:

2. NOSE EXAMINATION

External appearance

Weber's test:

Absolute Bone Conduction test:

FACIAL NERVE EXAMINATION:

3. NOSE EXAMINATION

External appearance

- Root
- Bridge
- Dorsum

- Alae
- Tip
- Columella

Cold spatula test

Anterior Rhinoscopy

Posterior Rhinoscopy

Paranasal Sinus Examination

3) THROAT EXAMINATION:

4) NECK EXAMINATION:

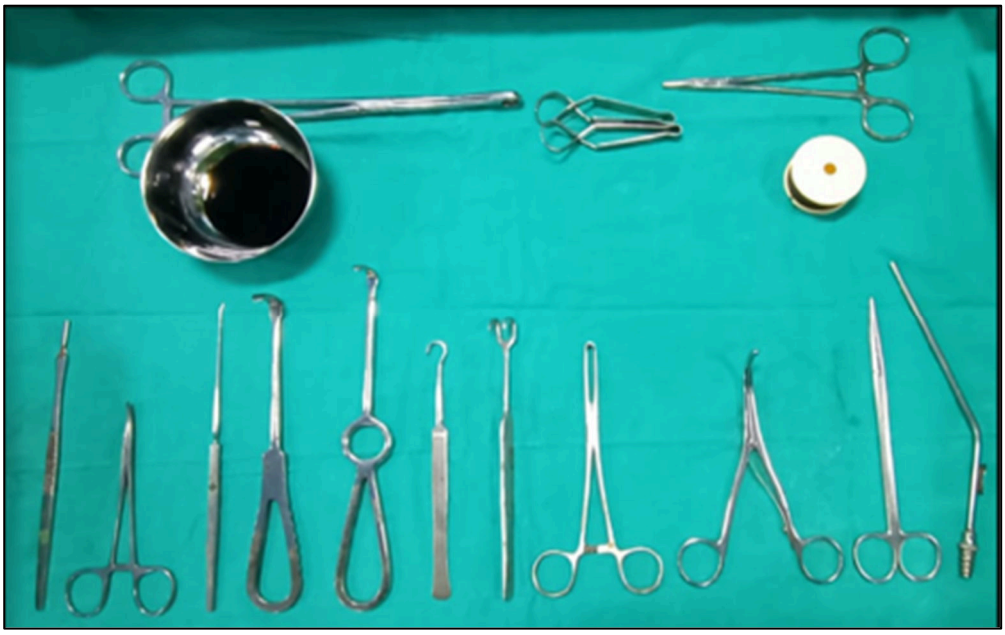
II) LOCAL EXAMINATION:

- Post -operative day
- Mode of ventilation
- Tracheostomy tube size
- Cuffed / uncuffed
- Dressing
- Soakage Secretion

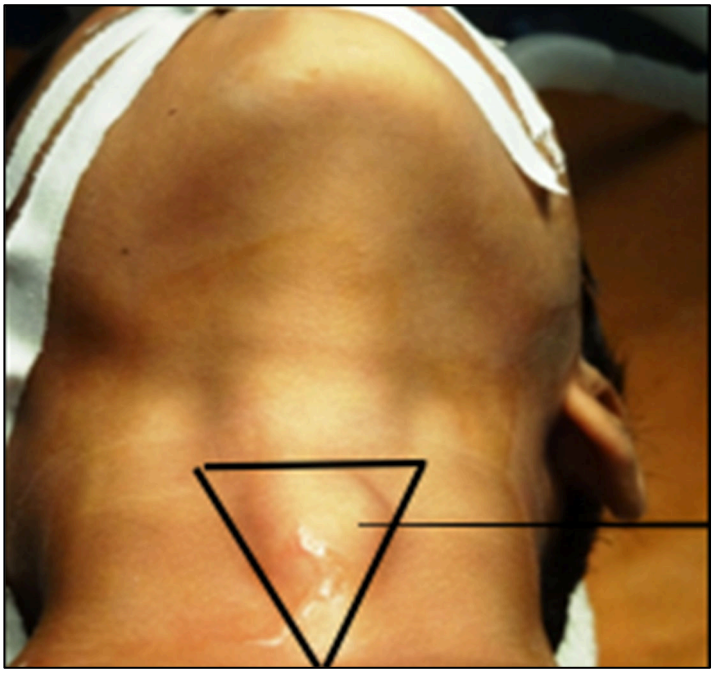
	DAY 0	DAY 5	DAY 10
Gram-negative bacilli			
Klebsiella pneumonia			
Pseudomonas aeruginosa			
Escherichia coli			
Acinetobacter baumanii			
Pseudomonas cepacia			
Gram-positive cocci			
Staphylococcus aureus			
Stahylococcus epidermidis			
Streptococcus viridans			
Others			
Fungi			
Candida albicans			
Candida parapsilosis			
Aspergillus			

ANNEXURE IV

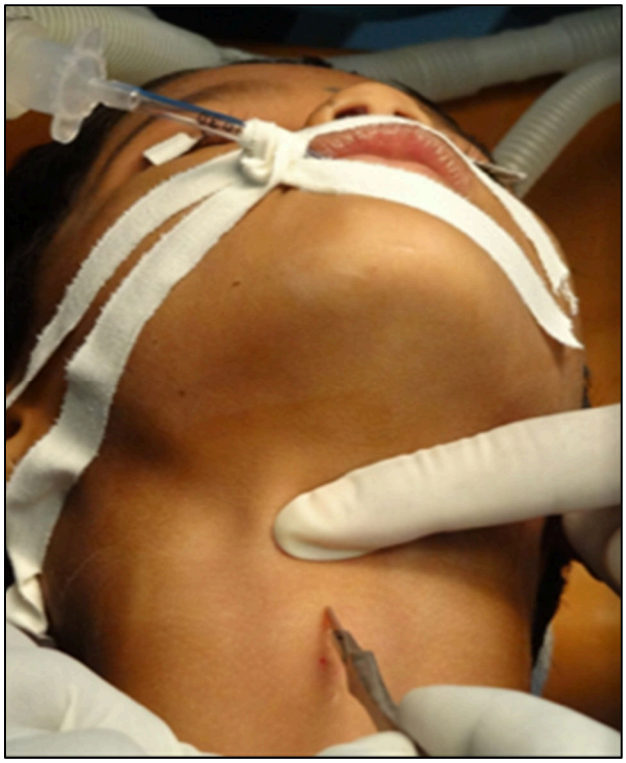
PHOTOGRAPHS



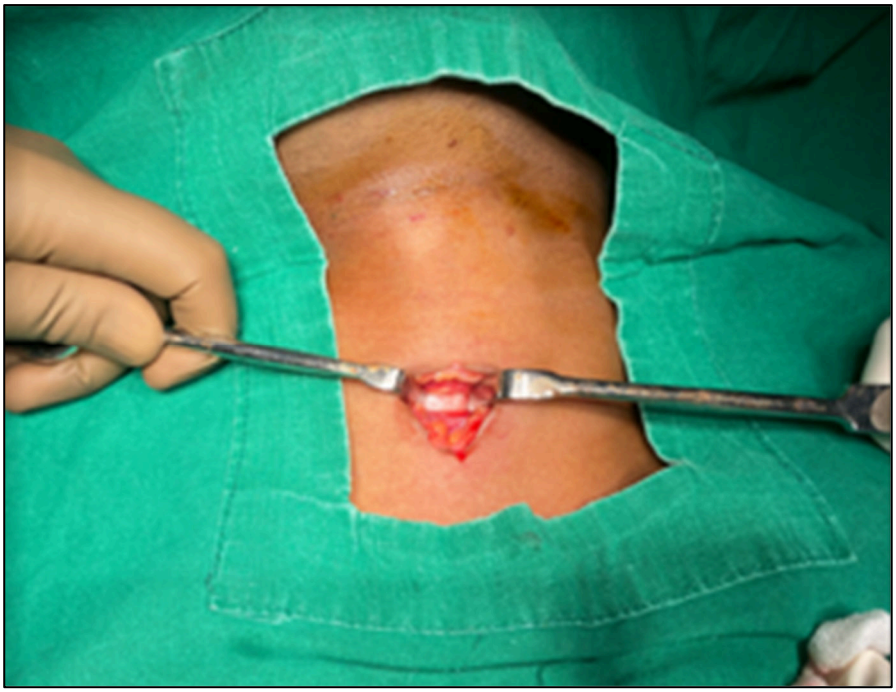
Photograph 1: Tracheostomy Instruments



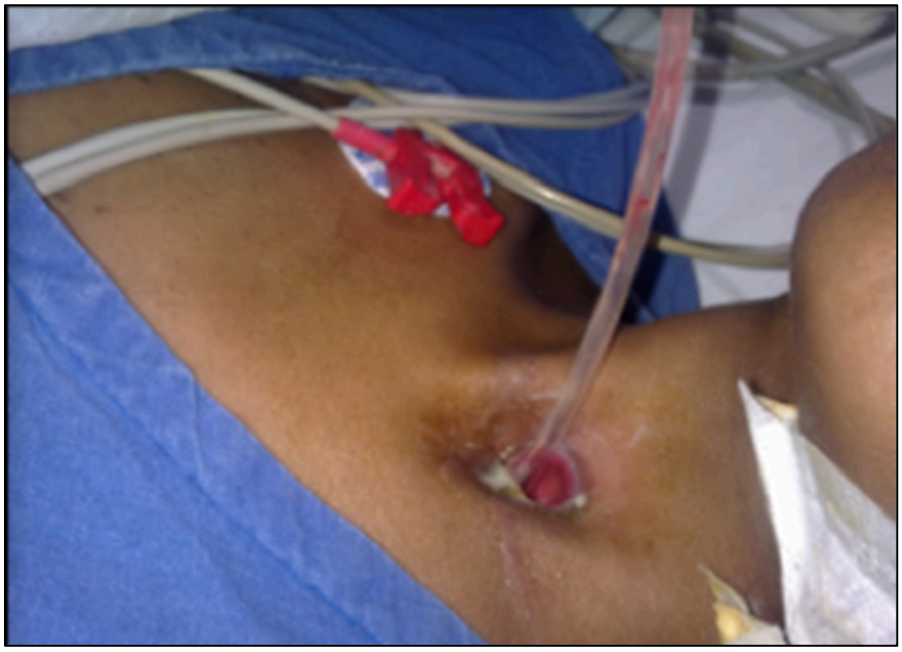
Photograph 2: -Infiltration of Jackson's triangle



Photograph 3:- Vertical Midline Incision



Photograph 4:- Trachea Identified and Confirmed



Photograph 5:- Collection of Tracheal Aspirate under Direct

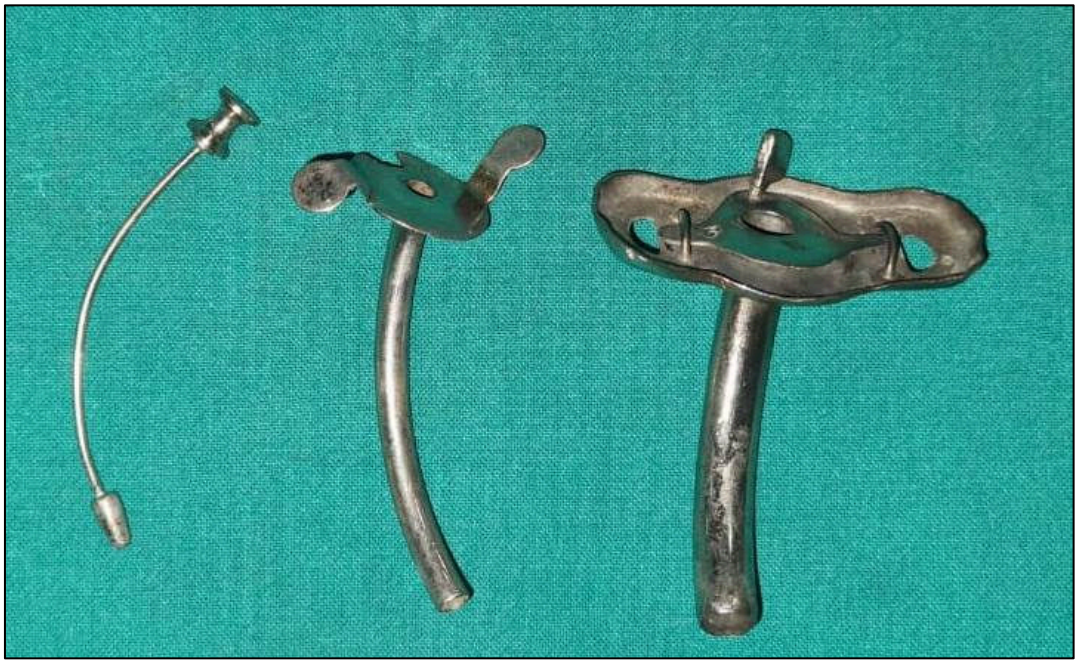
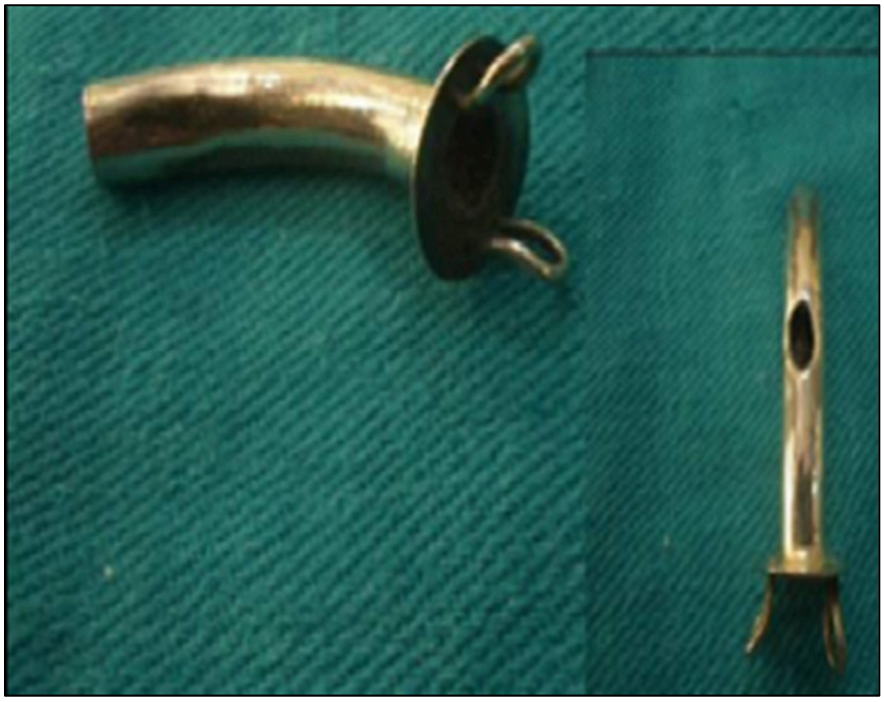
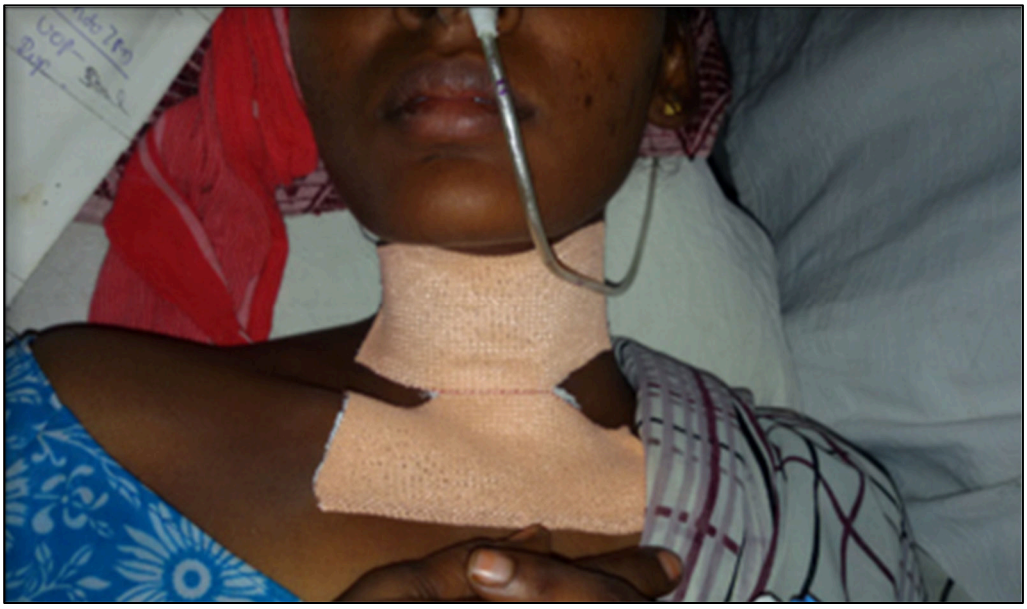


Photo 6:- Jackson's Metallic Tube



Photograph 7: Fuller's Bi-flanged metallic tube



Photograph 8: Decannulation

ANNEXURE V - KEY TO MASTER CHART

F	:	Female
M	:	Male
LA	:	Local Anesthesia
GA	:	General Anesthesia
SAH	:	Sub Arachnoid Hemorrhage
DM	:	Diabetes Mellitus
IVH	:	Intra ventricular Hemorrhage
ICB	:	Intra cranial Bleed
SDH	:	Subdural Hematoma
MMA	:	Middle Meningeal Artery
RTA	:	Road Traffic Accident
HTN	:	Hypertension
GB	:	Guillain -Barre syndrome
TB	:	Tubercular

SR NO	AGE/SEX	DIAGNOSIS	TYPE OF	TYPE OF	DAY 0	DAY 5	DAY10
			ANESTHESIA	**TRACHEOSTOMY TUBE**			
1	40/M	Case of Drug Induced Cougulopathy	LOCAL	PORTEX CUFFED	K pneumonia	P aeruginosa	Citrobacter freunddi
2	35/F	SDH	GA	PORTEX CUFFED	P aeruginosa	Acinetobacter baumanii	E coli
3	70/F	Meningitis of Viral Origin	LOCAL	PORTEX CUFFED	P aeruginosa	P aeruginosa	Burkholderia cepacia
4	60/M	Stroke MMA	LOCAL	PORTEX CUFFED	K pneumonia	K pneumonia	K pneumonia
5	55/M	Tuburcularlar Meningitis	GA	PORTEX CUFFED	K pneumonia	K pneumonia	K pneumonia
6	60/M	SAH	GA	PORTEX CUFFED	Serratia Marcescense	K pneumonia	P aeruginosa
7	55/M	Brain Infract	GA	PORTEX CUFFED	enterococcus casseliflavus	P aeruginosa	P aeruginosa
8	67/F	SDH	LOCAL	PORTEX CUFFED	No organism	K pneumonia	No organism
9	23/M	Case of Drug Induced	LOCAL	PORTEX CUFFED	Sterile organism	Citrobacter freunddi	P aeruginosa
		Cougulopathy with Pontine Bleed					
		with Aspiration					
10	21/M	GB Syndrome	LOCAL	PORTEX CUFFED	K pneumonia	Acinetobacter baumanii	K pneumonia
11	23/M	GB with Bronchopneumonia	LOCAL	PORTEX CUFFED	No organism	K pneumonia	Acinetobacter baumanii

SR NO	AGE/SEX	DIAGNOSIS	TYPE OF	TYPE OF	DAY 0	DAY 5	DAY10
12	35/M	SDH with Lobar Pneumonia with IDH	LOCAL	PORTEX CUFFED	P aeruginosa	K pneumonia	P aeruginosa
13	45 /M	RTA Frontal Cranitomy	LOCAL	PORTEX CUFFED	Coagulase -ve Staphy sp.	K pneumonia	K pneumonia
14	42/F	SDH	LOCAL	PORTEX CUFFED	K pneumonia	K pneumonia	K pneumonia
15	23/M	Post Hysterectomy Pulmonary	GA	PORTEX CUFFED	Klebsella oxytoca	Coagulase -ve Staphy sp.	Acinetobacter baumanii
		Thromoembolism					
16	23/M	Thalamic Bleed IVH	LOCAL	PORTEX CUFFED	K pneumonia	Enterobacter clocae	Enterobacter clocae
17	28/M	Intra Cranial bleed with HTN	LOCAL	PORTEX CUFFED	K pneumonia	Staphy epidermis	E coli
18	28 /M	Intra Cranial Bleed	LOCAL	PORTEX CUFFED	K pneumonia	K pneumonia	Enterococcus faecalis
		with HTN					
19	67/M	Intra Cranial Bleed	GA	PORTEX CUFFED	No organism	Candida species	P aeruginosa
20	56/F	ICD with type 2 DM	LOCAL	PORTEX CUFFED	K pneumonia	P aeruginosa	P aeruginosa
21	45/M	GB Syndrome	LOCAL	PORTEX CUFFED	Streptococcus Pyogene	P aeruginosa	St aureus
22	23/M	ICB	LOCAL	PORTEX CUFFED	K pneumonia	K pneumonia	No organism

SR NO	AGE/SEX	DIAGNOSIS	TYPE OF	TYPE OF	DAY 0	DAY 5	DAY10
23	55/M	SAH	GA	PORTEX CUFFED	K pneumonia	P aeruginosa	P aeruginosa
24	25/F	ICB	GA	PORTEX CUFFED	No organism	K pneumonia	P aeruginosa
25	43/M	Case of Meningoencephalocele	LOCAL	PORTEX CUFFED	No organism	No organism	P aeruginosa
26	61/M	TB Meningitis	GA	PORTEX CUFFED	St epidermis	Enterobacter	Enterococcus faecalis
27	18?F	GB Syndrome	GA	PORTEX CUFFED	No organism	No organism	P aeruginosa
28	61 /M	Brain Infract	GA	PORTEX CUFFED	St epidermis	Enterobacter clocae	P aeruginosa
29	51 /M	GB Syndrome	GA	PORTEX CUFFED	E coil	K pneumonia	K pneumonia
30	21/M	Stroke	GA	PORTEX CUFFED	No organism	Enterococcus	P aeruginosa