

**“A STUDY OF PRIMARY AND SECONDARY
TRACHEOESOPHAGEAL VOICE PROSTHESES IN TOTAL
LARYNGECTOMY”**

This dissertation is submitted to

THE TAMILNADU Dr. MGR MEDICAL UNIVERSITY

In partial fulfillment of the requirements for

MS ENT

Branch IV Degree Examination 2022



**UPGRADED INTITUTUE OF OTORHINOLARYNGOLOGY
MADRAS MEDICAL COLLEGE
CHENNAI-600 003.**

MAY- 2022

REGISTRATION No.: 221914002

BONAFIDE CERTIFICATE

This is to certify that this dissertation entailed “*A STUDY OF PRIMARY AND SECONDARY TRACHEOESOPHAGEAL VOICE PROSTHESES IN TOTAL LARYNGECTOMY*” submitted by **Dr.ABIRAMI C**, appearing for M.S. ENT., Branch IV Degree examination in May 2022 is a bonafide record of work done by her under my direct guidance and supervision in partial fulfillment of regulations of the Tamil Nadu Dr. M.G.R. Medical University, Chennai, Tamil Nadu, India.

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CERTIFICATE – II

This is to certify that this dissertation work titled “*A STUDY OF PRIMARY AND SECONDARY TRACHEOESOPHAGEAL VOICE PROSTHESES IN TOTAL LARYNGECTOMY*” of the candidate Dr.ABIRAMI C, with registration Number 221914002 for the award of M.S in the branch of Otorhinolaryngology. I personally verified the urkund.com website for the purpose of plagiarism check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows 10 percentage of plagiarism in the dissertation.

Guide & Supervisor sign with Seal.

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DECLARATION

I solemnly declare that the dissertation “**A STUDY OF PRIMARY AND SECONDARY TRACHEOESOPHAGEAL VOICE PROSTHESES IN TOTAL LARYNGECTOMY**” is done by me at the Madras Medical College and Government General Hospital, Chennai during 2019-2022 under the guidance and supervision of **Prof.Dr.F.ANTHONY IRUDHAYARAJAN M.S., D.L.O.,**

This dissertation is submitted to The Tamilnadu Dr. M.G.R. Medical University, towards partial fulfillment of regulation for the award of **M.S. DEGREE IN OTORHINOLARYNGOLOGY (BRANCH-IV).**

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ABBREVIATIONS

TEP	:	TRACHEOESOPHAGEAL PUNCTURE
MRND	:	MODIFIED RADICAL NECK DISSECTION
SCC	:	SQUAMOUS CELL CARCINOMA
USG	:	ULTRASONOGRAPHY
CT	:	COMPUTED TOMOGRAPHY
PES	:	PHARYNGOESOPHAGEAL SEGMENT
VP	:	VOICE PROTHESIS
TT	:	TOTAL THYROIDECTOMY
TL	:	TOTAL LARYNGECTOMY
LEMG	:	LARYNGEAL ELECTROMYOGRAPHY
HRS	:	HARRISSON ROBILLARD SCHLTZ RATING SCALE
VHI	:	VOICE HANDICAP INDEX

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BACKGROUND

Tracheoesophageal puncture and placement of voice prosthesis have become the effective method of choice to achieve voice rehabilitation after total laryngectomy.

A study has been conducted in post laryngectomized patient who undergone either primary and secondary tracheoesophageal puncture with insertion of voice prosthesis and speech therapy.

These patients are followed up to our institution for every 3 months or longer to compare the complications of tracheoesophageal puncture and success rate in functional outcome of voice rehabilitation .

AIMS AND OBJECTIVES

- To study the complications in primary and secondary tracheoesophageal puncture following total laryngectomy
- To determinate the success rate of functional voice outcome in primary and secondary tracheoesophageal voice prostheses.

STUDY PLACE :

Rajiv Gandhi Government General Hospital, Chennai – 600003

COLLABORATING DEPARTMENT :

Upgraded Institute of Otorhinolaryngology

STUDY DESIGN : Retrospective and Prospective study

STUDY PERIOD : November 2020 to December 2021

SAMPLE SIZE : 20

INCLUSION CRITERIA :

- Age group :40 to 75 years
- Both sex male and female
- Patient undergoing total laryngectomy for the treatment of laryngeal malignancy
- Adequate pulmonary reserve
- Post laryngectomy stoma healthy

EXCLUSION CRITERIA :

- Age group < 40 years
- Recurrence carcinoma
- Multiple metastasis in head and neck
- Inadequate pulmonary reserve
- Extensive surgery involving pharynx and larynx with separation of tracheoesophageal party wall
- Impaired hand dexterity

MATERIALS AND METHODS :

A Prospective and Retrospective study was carried out with 20 patients who underwent total laryngectomy subjected to voice rehabilitation by the placement of voice prostheses by means of tracheoesophageal puncture at Upgraded Institute of Otorhinolaryngology , Rajiv Gandhi Government General Hospital , Chennai. Patients were divided into two groups according to the type of tracheoesophageal puncture received , who were implanted with blom singer duckbill voice prostheses immediately (primary TEP) or after(secondary TEP) the surgery.

This analysis includes the characteristics of the patients (age, gender, tumor site, stage of disease, type of surgery , use of radiation therapy), VP lifetime, complications for valve removal including surgical

and prosthetic related complications , functional outcome of voice measured by means of HRS rating scale and VHI score.

Surgical related complications are development of large and deep tracheotomy hole, pharyngoesophageal stenosis, granulation and cutaneous infection.

Prosthetic related complications are leakage, granulation tissue around prosthesis, candida infection, dislodgement of prosthesis.

Functional outcome of voice were recorded using Harrison – Robillard Shultz rating scale for about 6 months postoperatively or longer. It defines success by means of 3 parameters scores on 1 to 5 points : Use (degree to which tracheoesophageal speech used as main means of communication), Quality (the ease of voice production and it effect on its effect on intelligibility) , Care (degree of patients independence from professional aid for maintenance of fistula and prosthesis). An overall score of 12 or more is considered successful voice prosthesis rehabilitation.

The impact of the voice impairment in the patients life was assessed with Voice Handicap Index (VHI).This consist of a set of questionnaire which has 3 parts that is functional , emotional and physical parts. Each part has 30 questions and each has a value of one and the maximum disability is 120 and minimum for normal person is below 10.

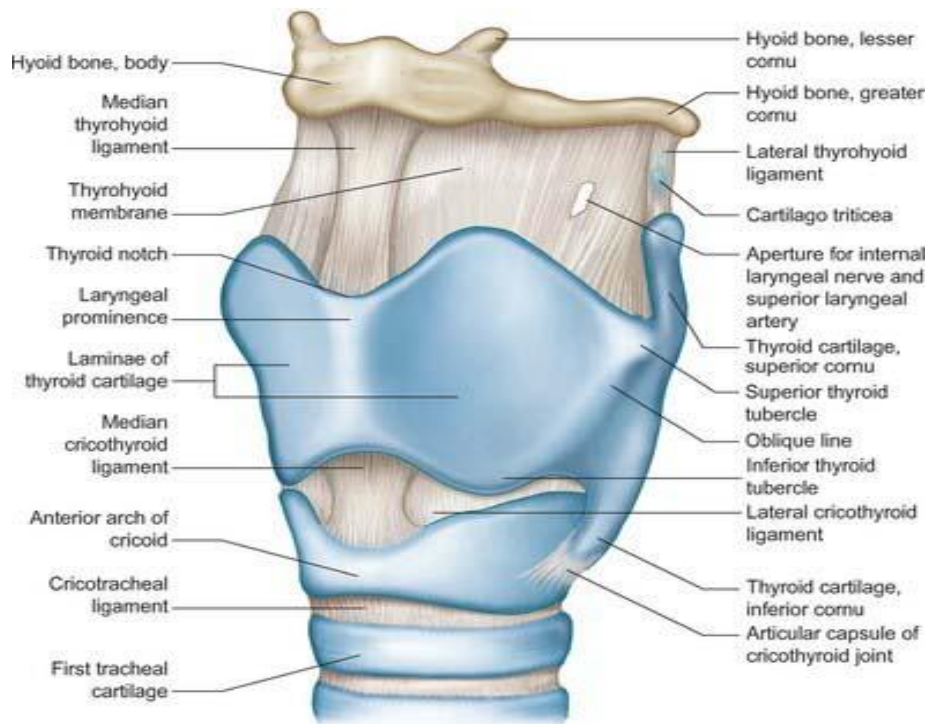
INTRODUCTION

EMBRYOLOGY OF LARYNX :

The development of larynx begins at the fourth week of gestation . It is developed from the midline ventral respiratory diverticulum of the foregut known as the laryngotracheal groove. This groove deepens gradually and fused to form a septum .This septum separates the laryngotracheal tube from the larynx and esophagus. The laryngotracheal tube formed that fuse caudally and extend cranially. The upper end communicate with the pharynx and forms the larynx and trachea. The lower end elongates and divides into two from which two main bronchi develop.

The thyroid cartilage develop from the ventral ends of the fourth arch cartilage. The epiglottis develops from the posterior part of the hypobranchial eminence. Other cartilages like arytenoid, corniculate and cuneiform from sixth arch cartilage. Cricoid cartilage and trachea are from the sixth branchial arch.

LARYNGEAL FRAMEWORK :



Larynx acts as tubular air passage , sphincter , organ of phonation.

It is composed of articulated cartilages interconnected by ligaments and muscles. It lies in front of C3 to C6 vertebrae in men . Slightly higher in women and children. Above opens into laryngopharynx and below into trachea.

CARTILAGES OF LARYNX:

The cartilages of larynx divided into paired and unpaired cartilages

3 paired cartilages : Arytenoid ,corniculate and cuneiform

3 unpaired cartilages : Epiglottis ,Thyroid and Cricoid

THYROID CARTILAGE :

Consist of two pentagonal plates which meets anteriorly in the midline to form an angle of 90 degree in male and 120 degree in female . Shield in shape. There is superior and inferior thyroid notch , posteriorly the lamina diverges to form superior and inferior cornua. Thyroid cartilage is covered by outer thick perichondrium and inner thin perichondrium and mucous membrane. Fusion of anterior end of two vocal ligaments form anterior commissure. There is oblique line which extend from superior thyroid tubercle to inferior thyroid tubercle. Structures attached to the oblique line are thyrohyoid , sternohyoid and inferior constrictor muscle

CRICOID CARTILAGE :

Complete ring and signet ring shaped cartilage with a narrow anterior arch and broad posterior lamina . This lamina has facets for articulation of arytenoid cartilage and inferior cornu of thyroid cartilage. It forms inferior part of anterior and lateral wall and most posterior part of larynx. Vertical ridge in midline of lamina forms attachment of longitudinal muscles of esophagus

EPIGLOTTIC CARTILAGE :

It is a leaflike , yellow elastic cartilage form anterior wall of laryngeal inlet. Thyroepiglottic ligament connect it to thyroid cartilage and hyoepiglottic ligament connects it to the hyoid superiorly which divides into suprahyoid and infrahyoid epiglottis. Anterior surface of epiglottis form mucous membrane superiorly and posterior wall of vallecula, posterior surface contain numerous pits into which mucus gland opens .This is the weak area through which tumor from posterior surface spread anteriorly

ARYTENOID CARTILAGE :

These are paired pyramidal shaped cartilage placed close together on upper and lateral border of cricoid lamina.It has three surfaces and two processes, an apex and base.

CORNICULATE CARTILAGE :

It is horn shaped elastic fibrocartilage articulate with apex of arytenoid.

CUNEIFORM CARTILAGE :

It is fibroelastic cartilage is found one in each margin of aryepiglottic fold.These cartilage provide rigidity to the membranes.

MEMBRANES OF LARYNX

Extrinsic membrane :

- 1) Thyrohyoid membrane
- 2) Hyoepiglottic ligament
- 3) cricotracheal membrane

Intrinsic membrane :

- 1) Upper quadrangular membrane
- 2) Lower cricovocal membrane

QUADRANGULAR MEMBRANE :

The membrane extends from epiglottis and arytenoid cartilage posteriorly. Upper border of the membrane is a free edge corresponding to aryepiglottic fold. Its lower edge is also free and extends from the epiglottis to the vocal process of arytenoid. It is also known as ventricular bands. The upper and lower edges of this membrane thicken to form aryepiglottic ligament and the vestibular ligament respectively.

CRICOVOCAL MEMBRANE :

It is a triangular fibroelastic membrane. The free upper edge of this membrane forms the vocal ligament, which stretches between the middle of the thyroid angle to the vocal process of arytenoid cartilage. Its lower border is attached to

arch of cricoid cartilage .These two sides of cricovocal membrane forms conus elasticus. The anterior end of vocal ligament is attached to the thyroid cartilage forming the anterior commissure tendon called Broyles ligament. Anterior thickened part of conus elasticus forms the cricothyroid ligament.

MUCOUS MEMBRANE :

It continues with lining of pharynx above and below with trachea. It is closely adherent to the epiglottis, the aryepiglottic ligament and the vocal cords. The upper half of the posterior surface of the epiglottis, the upper part of the aryepiglottic folds, vocal cords and the posterior commissure are covered by squamous epithelium. The epithelium of larynx is lined by either squamous , ciliated columnar or transitional epithelium

MUSCLES OF LARYNX :

Intrinsic muscles:

A) Muscles acting on vocal cord :

Posterior cricoarytenoid, Lateral cricoarytenoid, Interarytenoid, Thyroarytenoid , Cricothyroid ,Vocalis

B) Muscles acting on laryngeal inlet :

Thyroepiglottis , Interarytenoid , Aryepiglottis

Extrinsic muscles :

A) Elevators :

Stylopharyngeus , Salpingopharyngeus , Palatopharyngeus , Thyrohyoid

B) Depressors:

Mylohyoid , Genioglossus, Stylohyoid , Digastric

POSTERIOR CRICOARYTENOID :

It is the sole abductor of the vocal cords. It originates from the posterior surface of lamina of cricoid cartilage and inserts into muscular process of the arytenoid cartilage . It is innervated by recurrent laryngeal nerve.

LATERAL CRICOARYTENOID MUSCLE :

It originate from arch of cricoid cartilage and inserts into muscular process of arytenoid directed upwards and backwards. Contraction of muscle adducts the vocal cords.

THYROARYTENOID MUSCLE:

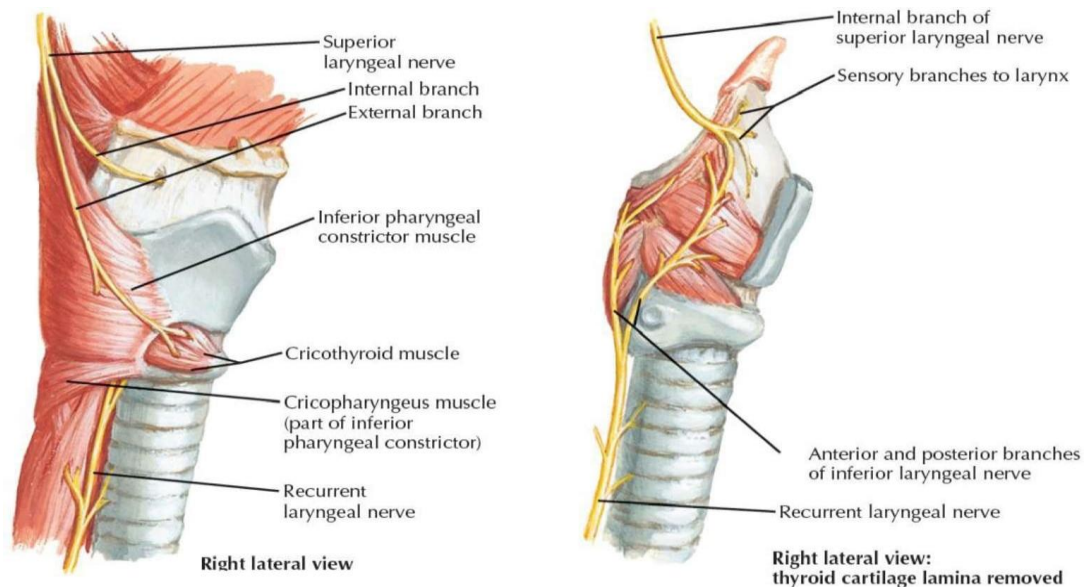
Vocalis muscle arises from medial section of thyroarytenoid muscle from the inner surface of the anterior surface of the thyroid

cartilage. It appears in the form of thin projection on front surface of vocalis process of the arytenoid cartilage. It controls the measurement of the tension and the length of the muscle fibres.

JOINTS OF LARYNX :

- Cricoarytenoid joint
- Cricothyroid joint

NERVE SUPPLY :



- Superior laryngeal nerve
- Recurrent laryngeal nerve

SUPERIOR LARYNGEAL NERVE :

The superior laryngeal nerve branches from the vagus nerve in neck at inferior end of nodose ganglion and it bifurcates into the internal and the external laryngeal nerve.

The internal laryngeal nerve enters into the larynx at the thyrohyoid membrane and supply the sensory innervation to the entire mucosa of the larynx above the vocal cords.

The external laryngeal nerve supply motor innervation to the cricothyroid muscle.

RECURRENT LARYNGEAL NERVE :

These are the main motor innervation to the larynx . On the left , recurrent laryngeal nerve usually loops under the aorta .On the right , loops under the brachiocephalic artery. It supplies laryngeal muscle like posterior cricoarytenoid, interarytenoid, lateral cricoarytenoid, thyroarytenoid .

SURGICAL ANATOMY :

The larynx is divided into three sites and each of these sites is divided into subsites .

✚ SUPRAGLOTTIS :

- Suprahyoid epiglottis
- Aryepiglottic fold
- Arytenoid
- Infrahyoid epiglottis
- Ventricular bands

✚ GLOTTIS :

- Vocal cords
- Anterior commissure
- Posterior commissure

✚ SUBGLOTTIS:

BLOOD SUPPLY AND LYMPHATIC DRAINAGE :

- Most of the parts of larynx are supplied by the superior laryngeal arteries.
- The region around the cricothyroid supplied by the inferior laryngeal artery.
- Posterior cricoarytenoid supplied by the posterior branch of inferior laryngeal artery.
- Supraglottis supplied by Superior laryngeal branch of the superior thyroid artery
- Subglottis supplied by Inferior laryngeal branch of the inferior thyroid artery.

Supraglottis - Level 2 and 3 and jugulo omohyoid nodes. Ventricular lymphatics also passes through cricothyroid membrane and ipsilateral thyroid gland to the level 3 and level 4 lymph nodes.

Subglottis - Lymphatics form three main trunks .

One superficial trunk pierces the cricothyroid membrane and drains into delphian nodes which inturns drain into the pre and paratracheal and supraclavicular nodes.

The two posterolateral trunks penetrate the cricotracheal membrane and terminate in the paratracheal node and mediastinum

Glottis – This is the watershed area with poor lymphatics. Anterior commissure drains into the prelaryngeal nodes.

Lymphatics drain unilaterally and the vocal folds have sparse lymphatics, therefore glottic cancer must invade deeply before they gain access to lymphatic channels

Supraglottis is formed without midline union , its lymphatic drain bilaterally.

Venous drainage is by the superior and inferior laryngeal veins which are the tributaries of the superior and inferior thyroid veins. Superior and inferior thyroid veins drain into the internal jugular vein and left brachiocephalic vein respectively.

NATURAL BARRIERS TO THE SPREAD OF TUMOR :

The laryngeal cartilages, Hyoepiglottic ligaments, Thyrohyoid membrane, Quadrangular membrane , Conus elasticus , Anterior commissure and Cricothyroid membrane

Superiorly , Hyoepiglottic ligament provides a barrier to spread of tumor to the tongue base.

FUNCTIONS OF LARYNX :

- 1) Protection (Swallowing, Protection and Reflexes)
- 2) Respiration and control of ventilation
- 3) Effort closure
- 4) Phonation

THEORIES OF PHONATION :

- 1) Neurochronaxic Hypothesis
- 2) Myoelastic – Aerodynamic Theory
- 3) Body Cover Principle
- 4) Two Mass Model
- 5) Source Filter Hypothesis
- 6) One Mass Model

AERODYNAMIC THEORY :

This theory postulates that the vocal cords are subjected to well established aerodynamic and physical forces. There is a building up of infraglottic air pressure and it acts on the vocal folds which are kept tensed by the tonic contraction of the laryngeal muscles. This increased infraglottic pressure forces the vocal cords apart and its set in vibration, once again the pressure falls, vocal cords recoil following which the subglottic pressure raises. The mode and frequency of vibration is dependent on properties of the cord and interplay of the intrinsic muscles of the larynx.

NEUROMUSCULAR OR CLONIC THEORY:

This states that each new vibratory cycles are initiated by nerve impulses transmitted from brain to the vocalis muscle by way of the vagus nerve. The frequency of vocal cord vibration is dependent on rate of impulses delivered.

PHYSIOLOGY OF PHONATION :

PULMONARY / PRE PHONATORY INSPIRATORY PHASE :

Rapid abduction of vocal cord



Allow intake of air



Adduction of Vocal cord



Contraction of thoracic and abdominal muscles



Increase subglottic air pressure overcomes the resistance of vocal cord

LARYNGEAL PHASE :

Phonation threshold pressure



Opening of Vocal cord



Release of small puff of air



Moving air vibrates the elastic Vocal cord

SUPRAGLOTTIC /ORAL PHASE :

Modulation of sound by lip , tongue, pharynx , palate and teeth



Production of Speech

REQUIREMENTS FOR PHONATION :

- 1) Adequate breath support
- 2) Approximation of vocal cords
- 3) Favorable vibratory properties
- 4) Favorable vocal cords / fold shape
- 5) Control of length and tension

LARYNGEAL CARCINOMA:

It is the second most common site of malignancy in head and neck and the eleventh most common form of cancer among men and worldwide. 85 to 95 % are squamosal cell carcinoma. Males are more common than female . Most common after the age of 60 and less common under 40. Loss of laryngeal function affects speech and swallowing.

Prevention and early diagnosis of laryngeal carcinoma is most effective means for increasing the cure rate and preserving function. Glottic carcinoma can be detected at an earlier stage than tumors located other subsites in head and neck.

RISK FACTORS :

- Tobacco and alcohol - the risk is proportional to the intensity and duration of tobacco or alcohol consumption
- The risk of developing laryngeal carcinoma is highest in current smokers and increases with the number of cigarettes smoked.
- Alcohol consumption is more important risk factor for supraglottic cancer whereas tobacco use is strongly associated with glottic cancer
- Laryngopharyngeal reflux : Alkaline bile reflux may also causative risk .
- Other toxins : Occupational exposure to toxins – Diesel exhaust , asbestos , organic solvents , sulphuric acid gas, mustard gas , metal dust , wood dust , stone dust , mineral wool and cement dust .
- Lower Socioeconomic status and manual ‘ blue collar’ also experience a higher risk of developing laryngeal cancer.
- Human Papilloma virus
- Genetic susceptibility : Fanconi anemia and congenital dyskeratosis

- Diet : Increase intake of fruits and vegetables and decrease intake of meat and fat

PATHOLOGY :

Squamous cell carcinoma is well known to arise from epithelial precursor lesion which may be localized or represent wider area of field of cancerization

Most recent WHO classification recommends laryngeal dysplasia are assigned as low and high grade categories

CLINICAL FEATURES :

GLOTTIC CANCER:

- Early symptoms : Dysphonia persisting for 3 weeks or more
- Late stage : Dyspnoea , Stridor signifies bulky of tumor , vocal cord fixation or subglottic extension with airway narrowing .
- Hemoptysis occur if there is any pulmonary involvement but this may be dangerous if primary laryngeal tumor is ulcerated.
- Glottic tumor remain localized in the glottis for prolonged period, owing to the natural barriers to tumor spread , ligaments , membrane and cartilages and to the relative paucity of glottic lymphatics

SUPRAGLOTTIC CANCER :

- Initial symptoms : Cervical lymphadenopathy without laryngeal symptoms
- Globus or foreign body sensation in throat
- As a tumor bulk increases , phonation is altered with a hot potato voice . If tumor extends to the cords, then hoarseness ensues.
- Late symptoms : Airway obstruction , dysphagia due to extension of tumor to the tongue base .

SUBGLOTTIC CANCER :

- Symptoms Present late
- Stridor
- Early symptoms can be globus or foreign body sensation in throat
- Any involvement of glottis or recurrent laryngeal nerve results in hoarseness.

The preoperative evaluation begin with history and physical examination with video directed laryngoscopy and biopsy for tissue diagnosis. Once the diagnosis was made, the physician and the patient together formulate an individualized plan based on tumor characteristics .Supraglottic tumor are always associated with evidence of cervical metastasis. The risk of

occult or evidence of tumor spread from supraglottic tumor with T1, T2, T3 and T4 tumor is 20 % , 40%, 60% and 80% respectively.

Finally the presence of squamous cell carcinoma of the head and neck places an individual risk of approximately a 15% to 20 % chance of developing a second primary within 5 years of initial diagnosis.

PHYSICAL EXAMINATION :

The patients general condition, socioeconomic status plays key role in making treatment decisions.

Assessment of a patients motor ability predicts success with a tracheoesophageal voice prosthesis. Thorough physical examination must be needed to high incidence if synchronous and metachronous primary lesions. Visual inspection with digital palpation needed for tumor involving the tongue base. If the node evidence of a second primary is found elsewhere in the oral cavity, oropharynx or hypopharynx , direct examination of larynx can be done.

NECK EXAMINATION :

Laryngeal carcinoma most frequently metastasized to nodal levels 2, 3 and 4 in the neck. Neck examination done for the evidence of direct extralaryngeal extension or metastatic disease. Bimanual palpation of all regions above the clavicle including central compartment of neck is to be

done. Careful assessment of the thyrohyoid membrane , thyroid cartilage and cricothyroid membrane and overlying laryngeal soft tissue may provide a more clinically useful assessment of the tumor than any advanced imaging analysis.

The term transglottic growth is given to a tumor involving glottis , supraglottis and subglottis with involvement of ventricle with vocal cord paralysis. In this lesion, it involves paraglottic space and associated with high incidence of neck disease and cartilage invasion

LARYNGEAL EVALUATION :

In patient presenting with hoarseness , visualization of larynx is essential. This is generally carried out in outpatient setting by indirect laryngoscopy using a mirror. Now this technique has been replaced by fiberoptic nasolaryngoscopy as the standard for laryngeal assessment .

The advantage of fiberoptic laryngoscopy is that the tongue base and posterior and lateral pharyngeal walls can be visualized and an impression of pyriform fossa obtained in addition to a detailed examination of the larynx .

IMAGING :

The main imaging modality for staging the larynx is CT scanning . It is used to complement direct examination of the larynx when staging

laryngeal cancers. Fine slice CT scanning provide a detailed impression of the extent of the tumor in particular the inferior extension, invasion of paraglottic space and pre epiglottic space and / or extension through the thyroid cartilage to the para laryngeal soft tissues. It can also identify possible nodal metastasis.

When assessing imaging of a laryngeal tumor , consideration should be given to the following :

- The subsites involved including extension across the midline and the approximate volume
- Para and pre epiglottic space extension
- Laryngeal cartilage invasion
- The subglottis and anterior wedge which can be particularly involved in anterior commissure tumors results in upstaging of tumors.
- An examination of pyriform fossa and post cricoid region should also be made.
- Tongue base involvement.
- Assessment of the neck , including central compartment for nodal metastases

Is there is any suspicion of lymph node involvement then this can be confirmed by ultrasound scanning with sampling by fine needle aspiration cytology or core biopsy as appropriate.

DIRECT LARYNGOSCOPY AND BIOPSY :

Initial assessment of the laryngeal structures is done using rigid laryngoscopy. This instrument is useful for navigating through and around tumor growth. Once this endoscope has been used to fully visualize the relevant structures and tumor extent, the larger rigid laryngoscope may be used. It is used to concentrate on laryngeal extent of the lesion after full assessment for synchronous or metachronous lesions the site , size and extent of the tumor , vocal cord mobility . The larynx is brought into complete view to visualize the extent of the lesion. A suspension apparatus is useful at this point – one to provide exposure and one to perform a biopsy are needed. The rigid telescope may be helpful in operative laryngoscopy evaluation of laryngeal tumors but this technique is greatly aided by securing the laryngoscope with a suspension bar. The telescope can be used during staging. These telescope provide superior visualization of the subglottis, the anterior commissure and the ventricle which are critical areas that may be difficult to assess adequately.

STAGING OF LARYNGEAL CARCINOMA:

TUMOR T STAGING :

SUPRAGLOTTIS :

T1	Tumor limited to one subsite of supraglottis with normal vocal cord mobility
T2	Tumor invades mucosa of more than one adjacent subsite of supraglottis or glottis or region outside the supraglottis (eg. Mucosa of the base of tongue , vallecula, medial wall of pyriform sinus) without fixation of the larynx
T3	Tumor limited to larynx with vocal cord fixation and / or invades any of the following : postcricoid area , preepiglottic space , paraglottic space and / or with minor cartilage erosion (inner cortex)
T4a	Tumor invades through thyroid cartilage , and / or invades tissue beyond the larynx e.g trachea, soft tissue of the neck including extrinsic muscles of the tongue , strap muscles , thyroid and esophagus
T4b	Tumor invades prevertebral space , mediastinal structures or encases carotid artery

GLOTTIS :

T1	Tumor limited to vocal cord (may involve anterior or posterior commissure) with normal mobility T1a – tumor limited to one vocal cord T1b – tumor involved both vocal cords
T2	Tumor extends to supraglottis and / or subglottis , and /or with impaired vocal cord mobility
T3	Tumor limited to larynx with vocal cord fixation and /or invades paraglottic space and /or with minor thyroid cartilage erosion
T4a	Tumor invades through thyroid cartilage or invades tissue beyond the larynx e.g trachea, soft tissue of neck including deep / extrinsic muscles of tongue , strap muscles , thyroid and esophagus
T4b	Tumor invades prevertebral space , mediastinal structures or encases carotid artery.

SUBGLOTTIS :

T1	Tumor limited to subglottis
T2	Tumor extends to vocal cord(s) with normal or impaired mobility
T3	Tumor limited to larynx with vocal cord fixation

T4a	Tumor invades through cricoid or thyroid cartilage and /or invades tissue beyond the larynx eg trachea , soft tissue of neck , strap muscles , thyroid and esophagus
T4b	Tumor invades prevertebral space , mediastinal structures and encases carotid artery

CLINICAL N STAGING :

NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single ipsilateral lymph node , 3 cm but not more than 6 cm in greatest dimension without extranodal extension
N2	N2a – metastasis in a single I\L lymph node , more than 3 cm but not more than 6cm in greatest dimension without extranodal extension N2b – metastasis in multiple ipsilateral lymph node none more than 6cm in greatest dimension without extranodal extension N2c – metastasis in bilateral or contralateral lymph node none more than 6cm in greatest dimension without extranodal extension
N3a	Metastasis in a lymph node mor than 6 cm in greatest dimension without extranodal extension

N3b	Metastasis in a single or multiple lymph node with clinical extranodal extension
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CLINICAL M STAGING :

M0 - No evidence of distant metastasis.

M1 - Distant metastasis.

STAGING GROUPING :

Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage II	T2	N0	M0
Stage III	T1 , T2	N1	M0
	T3	N0 , N1	M0
Stage IV A	T1 , T2 , T3	N2	M0
	T4a	N0. N1 , N2	M0
Stage IVb	Any T	N3	M0
	T4b	Any N	M0
Stage IVc	Any T	Any N	M1

PRINCIPLES OF MANAGEMENT OF LARYNGEAL CANCER:

95 % cases of laryngeal cancers are curable and treatable. Management of laryngeal cancer depends in the first instance on the stage of presentation. Variety of other factors also involved in decision making including the patients age , comorbidities , surgical access issues , the skills and preferences of the treating multidisciplinary team and the wishes of the patient.

Treatment plan classified into following groups

1. CURATIVE INTENT :

- Surgery
- Radiotherapy
- Surgery with postop chemoradiotherapy

2. REHABILITATION

- Voice rehabilitation
- Pulmonary rehabilitation
- Olfactory rehabilitation

3. PALLIATION

SURGICAL MANAGEMENT FOR LARYNGEAL MALIGNANCY :

The following types of procedures are in use now a days

1.VERTICAL PARTIAL RESECTION

- Cordectomy
- Frontal partial laryngectomy
- Lateral partial laryngectomy
- Frontolateral partial laryngectomy
- Extended frontolateral partial laryngectomy

2.HORIZONTAL PARTIAL RESECTION:

- Epiglottectomy
- Supraglottic partial laryngectomy
- Extended supraglottic partial laryngectomy

3.TOTAL RESECTION

- Total laryngectomy
- Total laryngectomy with partial pharyngectomy or partial glossectomy

The surgery of neck dissection can be combined with the above procedures

TOTAL LARYNGECTOMY :

HISTORY :

In 1866 – Patrick Watson credited with the first laryngectomy. It produces more complication and death of the patients. In 1873, Billroth of Vienna performed total laryngectomy on a patient with laryngeal malignancy. Bottini of Turin has the longest surviving recording of a total laryngectomy patient. Later two stage procedure was introduced by Gluck. First stage tracheal separation followed by second stage total laryngectomy after few weeks. In 1890, Sorenson student of Gluck proposed single stage procedure. Then, single stage procedure was proposed by Moure and Portmann in 1921.

INDICATION OF TOTAL LARYNGECTOMY :

- ✚ Advanced laryngeal malignancies with extensive cartilage destruction and extralaryngeal spread
- ✚ Involvement of posterior commissure or both arytenoids/cricoarytenoid joint tumor involvement , as is sometimes seen in advanced supraglottic tumors
- ✚ Circumferential submucosal disease – with / without bilateral vocal cord paralysis
- ✚ Subglottic extension with cricoid cartilage invasion
- ✚ Completion procedure after failed partial laryngectomy / irradiation

- ✚ Hypopharyngeal tumors originate at or spread to the postcricoid mucosa and advanced pyriform sinus cancers
- ✚ Massive neck metastases and thyroid tumors that invade both sides of the larynx from outside the laryngeal skeleton
- ✚ Advanced tumors of certain histologic types that are incurable by endoscopic resection , chemotherapy or RT (adenocarcinoma , spindle cell carcinoma, soft tissue tumor and large cell neuroendocrine tumors)
- ✚ Extensive pharyngeal or tongue base resections in patients who are at risk for aspiration.
- ✚ Severe irreversible aspiration, with the laryngectomy used for complete separation of the air and food passages.
- ✚ Radiation necrosis of larynx unresponsive to antibiotics or hyperbaric oxygen therapy

SELECTION CRITERIA :

- ✚ Patient should be fit for general anaesthesia.
- ✚ Patient should be motivated for post surgical life.
- ✚ Hands and fingers should be dexterous since handling of tracheostomy tubes need to be done on daily basis.
- ✚ Positive biopsy.
- ✚ Screening for metastasis.

✚ Second primary to be ruled out in all these cases.

PROCEDURE:

Under general anaesthesia , proper positioning provides access to the anterior part of the neck for the surgeon and assistant. For access to the larynx , a curved horizontal neck skin incision is preferred because of its minimal intersection with the pharyngeal closure and its potential for extension laterally into a neck dissection incision.

Once the incision is deepened, platysma and flaps are elevated superiorly and inferiorly in the subplatysmal plane , until exposure extends above to the upper border of the hyoid bone and below to the cervical trachea. Anterior jugular vein and delphian node is left undisturbed. They can be removed along with specimen . Then, medial border of sternocleidomastoid identified on each side. General investing layer of cervical fascia is incised vertically from the hyoid bone above to the clavicle below.

SKELETONIZATION OF LARYNX :

Division of the strap musculature after elevation of a subplatysmal flap. The omohyoid is divided inferiorly , usually during the neck dissection, the sternothyroid and sternohyoid muscles are divided inferiorly to expose the thyroid gland and trachea.

Division of suprahyoid musculature is performed and staying close to the superior aspect of hyoid bone. Cautery is avoided lateral to lesser cornu to avoid injury to hypoglossal nerve. In this area, the hyoid is retracted in such a way as to distract the greater cornu inferiorly and scissors are used to release the cornu staying right on the bone.

Division of constrictor muscle along the lateral aspect of the thyroid cartilage and dissection of the thyroid. If the thyroid to be resected, it is elevated and the dissection proceeds directly to the tracheoesophageal groove . If the thyroid to be preserved, the lobe is dissected away from the tracheoesophageal groove after division of the isthmus. The degree of skeletonization depends on tumor extent. Once the thyroid cartilage is skeletonized , the superior laryngeal neurovascular bundle can be divide to decrease the bleeding during the resection posterior border of thyroid cartilage is rotated anteriorly.

Constrictor muscles released from superior and inferior cornu by sharp dissection . Laryngeal branch of superior thyroid artery should be identified and ligated before it penetrate the thyrohyoid membrane.

ENTRY INTO LARYNX AND INITIAL TUMOR CUTS :

The pharyngotomy incision and definitive laryngeal removal are now performed to avoid contact with the neoplasm or cutting through its submucosal extensions. The pharynx is entered contralateral to the tumor. If superior extension to tongue base present , lateral pharyngotomy behind the thyroid cartilage performed . If the disease is confined below the level of the hyoid bone , then entry by the way of vallecula is feasible.

Mobilize the pyriform sinus and internal perichondrium from the thyroid cartilage . This should not be performed if the pyriform sinus is likely to be involved by the tumors . The trachea is transected and the ligamentous attachments are divided to permit dissection of the trachea away from the upper esophagus to the level of the posterior cricoarytenoid musculature.

Dissection follows the hyoepiglottic ligament to the epiglottis and vallecula to avoid entry into the pre epiglottic space. If clinically uninvolved, the vallecula is entered on the nontumor side and if the epiglottis is not involved, its tip is grasped.

Then the pharyngoepiglottic fold cuts are extended. Previously preserved pyriform sinus mucosa is preserved by transecting the mucosa close to the aryepiglottic fold. This leaves the larynx pedicled only on the mucosal side of the mucosal side of the anterior esophageal inlet, which

can be transected under direct vision to preserve such mucosa . If the trachea was not previously transected , it is done at this time to release the specimen.

COMPLETION OF TUMOR RESECTION AND REMOVAL OF LARYNX :

From above downwards, the epiglottis is held with a forceps and pulled forwards . Pharyngeal mucosa cut laterally with scissors on both sides of epiglottis aiming towards the superior cornua of thyroid cartilage. Constrictor muscles are divide along the posterior edge of the thyroid cartilage. Lateral cuts are joined by horizontal cuts. Horizontal cut is given just below the level of arytenoid cartilages. Larynx separated by incising the tracheal rings between 1st and 2nd ring.

PHARYNGEAL CLOSURE :

Pharynx is closed in the shape of T by connel suture. Suture knots should be inside. Pharyngeal closure can be reinforced using cervical fascia and muscle layers. Skin flap repositioned. Flap is sutured after anchoring the tracheostome. Suction drain is placed in the neck to prevent hematoma formation that could compromise the flap.

POSTOPERATIVE MANAGEMENT

Specific treatment of early post laryngectomy patients includes monitoring of systemic vital signs, fluid balance , oxygenation , wound drain vacuum retention and output, neck flap viability.

Postoperative treatment includes ventilator assistance based on respiratory status, tracheostomy tube care, airway humidification , chest physiotherapy, suture line care three times daily, nasogastric or tracheoesophageal fistula feed. Oral feed normally begun 7 days after surgery.

COMPLICATIONS OF TOTAL LARYNGECTOMY :

EARLY COMPLICATIONS

1. Drain failure
2. Hematoma
3. Infection
4. Pharyngocutaneous fistula
5. Wound dehiscence

LATE COMPLICATIONS

1. Stomal stenosis
2. Pharyngoesophageal stenosis and stricture
3. Hypothyroidism

REHABILITATION AFTER TOTAL LARYNGECTOMY

- Voice rehabilitation
- Pulmonary rehabilitation
- Olfactory rehabilitation

VOICE REHABILITATION:

Despite advances in conservative laryngeal surgery and radiotherapy. Laryngectomy still remains the procedure of choice for advanced stage laryngeal carcinoma and relapse after radiotherapy. The procedure results in a life long stoma, loss of normal voice, loss of nasal function and lung function changes.

Functional rehabilitation of patients has improved in the last two decades as increasing emphasis on primary voice restoration and quality of life have become as important as cure and survival.

TYPES OF ALARYNGEAL SPEECH :

For normal speech, a moving column of air from the lungs is exhaled through the adducted vocal cord producing a tone which was modified by articulators into speech. Following laryngectomy, not only vibratory source removed but the air supply is disconnected from articulators .

- EXTERNAL SOUND SOURCE (Eg . electrolarynx , cooper rand)
- OESOPHAGEAL SPEECH
- SURGICAL SHUNT (Eg . Stafferis , Amatus)
- VALVED PROSTHESIS (Eg . Blom singer , Groningen , Provox)

ELECTROLARYNX :

There are two types of electrolarynx namely an external type and oral type.

External type – It is placed against the neck and sound vibration is transmitted through a metal or plastic head on the device and transmitted through the tissue in the pharynx , hypopharynx and oral cavity and then articulated normally.

Oral type – A small tube is placed in the oral cavity and the generated sound is then articulated. It is more useful in postoperative type when neck tenderness is more.

The main advantages of the electrolarynx are its relatively short learning time, the ability to use immediately postoperatively and relatively low cost and its minimal maintenance.

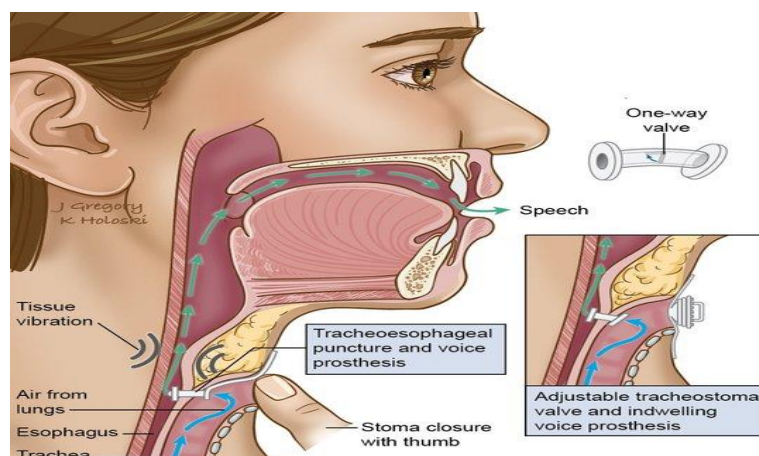
The main disadvantages are mechanical , monotonous and robot like sound quality , the necessity to use a hand to operate the controls and dependence on batteries.

OESOPHAGEAL SPEECH :

Oesophageal speech was the mainstay of alaryngeal communication and has been used as a method of voice restoration . It entails trapping air in the mouth or pharynx and propelling it into the esophagus. The patient can then reflux the air up through the esophagus , vibrating the pharyngeal mucosa or pharyngo-esophageal segment. This produces a belch like sound that can be articulated by the tongue, lips and teeth.

The main advantages are simple method and it requires no batteries and no apparatus. It provides hands free speech. The main disadvantages are difficult to train, requires 30 to 50 hours of intense speech therapy. Success rate is poor and variable. voice quality is inferior , harsh and low pitched.

TRACHEOESOPHAGEAL VOICE USING VOICE PROSTHESIS :



The introduction of reliable voice prosthesis by Singer and Blom in 1980. The success rate of voice rehabilitation after laryngectomy has improved considerably. This technique involves creating a simple TEP between the posterior wall of the tracheostome and the upper esophagus into which a one way valve is inserted. This one way valve prevents salivary and liquid soiling the airway. Occlusion of the stoma allows air during exhalation to be shunted into the pharynx then, sound is produced by vibrating the mucosa of the PE segment. Speech is then produced by articulation of this sound in the oral cavity.

Initially puncture technique was used as a secondary procedure in patients with previous laryngectomy who failed to achieve esophageal speech.

Hamaker et al. in 1985 to incorporate the tracheoesophageal puncture at the time of laryngectomy as a primary procedure.

The main advantages are it is more quickly and easily attained, more intelligible and natural sounding and has improved intensity and duration of speech, achieving more words with one breath when compared to esophageal speech.

The gold standard for voice rehabilitation is the rapid restoration of near normal speech within 2 to 3 weeks of operation with primary TEP and voice prosthesis.

PHYSICAL REQUIREMENTS	LARYNGEAL SPEECH	ESOPHAGEAL SPEECH	TE SPEECH
INITIATOR	Lungs , 500 ml	Esophageal air , 40 to 70 ml	Lungs , 500 ml
VIBRATOR	Vocal cords	PE segment	PE segment
ARTICULATOR	Tongue , teeth , lips and soft palate	Tongue , teeth, lips and soft palate	Tongue , teeth , lips and soft palate

TYPES OF TRACHEOESOPHAGEAL PUNCTURE :

1. Primary tracheoesophageal puncture
2. Secondary tracheoesophageal puncture

PRIMARY TEP	SECONDARY TEP
Done at the time of surgery	Done 2 to 3 months after radiotherapy
Patients retain high motivation to speak	Patient may loss motivation and speech may be delayed
Voice outcome : 90 to 95 %	Voice outcome : 70 %

PRIMARY VOICE RESTORATION :

It is standard practice and patients undergoing laryngectomy should feel confident that they will be able to talk shortly after the surgery.

SURGICAL TECHNIQUE FOR PRIMARY TEP :

Once the larynx is removed, a myotomy of the upper esophageal sphincter is carried out. This is to avoid hypertonicity and spasm of these muscles during attempted phonation and to allow expansion of the upper esophagus providing an air reservoir below the PE segment. Then the puncture is positioned in the midline about 10 to 15 mm below the cut end of the posterior tracheal wall. The tip of pair of curved artery forceps is inserted through the pharyngeal defect and advanced into the upper esophagus just as far as the puncture site , tenting up the mucosa. Then , cut the mucosa and posterior tracheal wall with scalpel and grasp tip of nasogastric tube / foleys catheter. The catheter is anchored to the skin above the stoma at the end of the procedure.

PHARYNGEAL CLOSURE :

Horizontal or T shaped connel suture made. Relax upper esophagus so that it does not undergoes spasm when the air is injected through the valve. The thyropharyngeus muscle is then repaired to create a suitable tonic PE segment at the optimal site in the pharynx with good reservoir below it and wide resonating PE segment above it.

REPAIR OF SUPRAHYOID MUSCLES :

It is important to suture suprahyoid muscles down to the thyropharyngeus. This strengthens the mucosa above the repair thus avoiding a pseudoepiglottis and anterior pouch to avoid dysphagia.

REINNERVATION OF THE PHARYNX :

The cut end of superior laryngeal nerve and recurrent laryngeal nerve may be reimplanted into the muscular wall of the reconstructed pharynx and upper esophagus.

STOMA RECONSTRUCTION :

The size , shape and contour of the stoma and surrounding skin are important to aid digital occlusion of the stoma and help ensure optimal adhesion of the tracheostoma valve housing.in order to avoid tracheal retraction the trachea should not be transected too low and the margins of the trachea can be sutured to the medial margins of the sternomastoid muscles to secure it near the skin. If the tension of the sternomastoid muscle are prominent , they could be safely divided to ensure a smooth and circular stomal appearance.

SECONDARY VOICE RESTORATION :

The technique of TEP with prosthetic voice restoration was originally developed for those patients who had failed to achieve adequate oesophageal speech.

ASSESSMENT :

In post laryngectomy, the patients need a tonic PES to provide a satisfactory vibratory source for TE speech. Tonicity is best assessed with videofluoroscopy.

VIDEOFLUOROSCOPY :

The most reliable and accurate way of assessing PE segment physiology after laryngectomy. This has three components : a barium swallow , an esophageal insufflation test and attempted phonation

SELECTION CRITERIA FOR SECONDARY VOICE RESTORATION:

- Patient must be motivated.
- Patient should be mentally stable.
- Patient must have adequate understanding of post surgical anatomy and the TEP prosthesis.
- Patient should not have an alcohol or other substance dependency.
- Patient must demonstrate adequate manual dexterity and ability to manage prosthesis.

- Intact TE party wall
- Visual acuity
- Patient should not have significant pharyngeal stenosis or stricture
- Patient should demonstrate positive tonicity results following esophageal air insufflation test
- Patient must have adequate pulmonary support for prosthesis use
- Patient should have stoma of adequate depth and diameter for prosthesis.

SURGICAL TECHNIQUE OF SECONDARY TEP :

The method was described by singer and blom in 1980. The forceps are inserted alongside a pharyngeal speculum into the esophageal opening under direct vision and advanced down to the level of the tracheostome where the tip can be seen and palpated as it tents up the posterior tracheal wall in a similar way to primary puncture technique.

An incision made through the posterior wall of the stoma in the midline on to the tip of the forceps which are advanced into the trachea. The end of catheter (14 G) IS introduced into the forceps and withdrawn into the pharynx, passed caudally and released. The catheter is sutured to the skin above the tracheostome. It remain for 2 to 7 days. It is replaced with suitable prosthesis after measuring the length of the tract.

TYPE OF PROSTHESIS :



1. Non indwelling prosthesis
2. Indwelling prosthesis

NON INDWELLING	INDWELLING
Can be removed and replaced by the patients	Stay in place permanently and has to be replaced by a clinician
	More robust with large life span
Patient dexterity paly major role	Lesser role , shorter learning curve
	Clinician dependent and more initial cost
Eg. Blom singer duckbill, low resistance VP and panje	Eg.Groningen device, provox , blom singer

SELECTING A PROSTHESIS:

- Candidate dexterity
- Phonatory effort
- Thickness of the party wall
- Durability
- Cost

CANDIDATE DEXTERITY:

If the patient is unable or unwilling to change the valve independently, an indwelling style device offers more security from dislodgement.

PHONATORY EFFORT :

If the voice quality is effortless, loud and consistent, then the patient may do well with a higher resistance with increased durability. If the voice quality is strained and effortful, a lower resistance device of greater diameter may be appropriate.

THICKNESS OF THE PARTY WALL:

A too long prosthesis will cause a pistoning effect and consequently leakage around the prosthesis, while a too short prosthesis may result in aphonia.

DURABILITY :

If the device recurrently leaks in less than a couple of months with no treatable cause (eg. Candida infection), a device with higher resistance and should be considered.

COST :

Patients without prosthesis coverage in health insurance should be provided cost option when selecting a device.

TROUBLESHOOTING TE PUNCTURES :

- Non speaking
- Periprosthetic

NON SPEAKING :

CAUSE :

1. Device problem
2. PE segment spasm

REMEDY :

1. Rule out recurrence , clean the device insitu . If still no speech , remove the device and assess open shunt voice . If the shunt voice is normal then device needs replacement.

2. Assess with LEMG , lignocaine test or USG . If present , injection of botox is useful.

PERIPROSTHETIC LEAKAGE , NON SPEAKING :

CAUSE : Granulations

REMEDY : remove TEP and allow granulations to settle or remove with laser and reinsert prosthesis at a later stage.

PERIPROSTHETIC LEAKAGE ALONE :

CAUSE :

1. Pistoning due to longer TEP
2. Widened fistula

REMEDY : a silastic ring can be placed if still persistent then downsize the prosthesis

PERSISTENT LEAKAGE / FISTULA :

CAUSE : interactable fistula

REMEDY : surgical closure of fistula or a silicone obturator to close the defect.

The main reason a silicone valve starts to leak is growth of a biofilm on the valve that consist of bacteria and candida species which

prevents its proper closure. Consumption of probiotics such as yogurt which have been proven to be effective.

FIBROUS RING :

Forms doughnut around the tracheal end of the valve. If the ring is not too prominent, the tract can be resized and a longer valve fitted. Otherwise, excision of the fibrous ring is recommended.

VALVE EXTRUSION :

The prosthesis may become dislodged during cleaning or coughing etc. If not replaced immediately the tract will close down , a catheter or dilator can be used instead to keep the tract open until the prosthesis can be replaced. The more flimsy retention collars make them more prone to dislodgement from the TEP tract. If the prosthesis is completely extruded, it is important to check whether the dislodgement has occurred toward the trachea or into the esophagus – a proper flexible endoscopy of the trachea and if negative , radiologic examination must be conducted. for partial extrusion of prosthesis, rule out underlying infection of tissue hypertrophy.

PSEUDOVALLECULA :

Correction is easily achieved by endoscopic division of the web using a similar technique to excision of the cricopharyngeal bar in the pharyngeal pouch.

MICROSTOMIA :

The stoma can usually be dilated with buttons or laryngectomy tubes, but if the stenosis is well established it may be necessary to carry out a stomaplasty. The preferred technique is bilateral Y- V advancement with excision of scar tissue as necessary.

INADVERTENT OPENING OF THE VALVE :

Result of underpressure generated in the esophagus through the breathing and swallowing.

TRANSPROSTHETIC LEAKAGE :

The proper length of the device should be carefully checked by gently pulling with a hemostat at the tracheal flange . It is easy to assess whether the length is still correct or if the VP has become too long. The ability to move the device some 2 to 3 mm in AP direction is not only tolerable but signifies that mucosa of the TEP tract is not under undue pressure from the VP flanges more than 3 mm of movements is an indication to downsize the prosthesis one level.

ATROPY OF THE TEP / PARTY WALL :

Wide TEP Tract : Can also be caused by pressure necrosis or when the TE shunt is not created with an incision . Radiotherapy can also cause atrophy.

TREATMENT :

1. Shrinkage
2. Silicone washer
3. Purse string suture : if the tissue is not too atrophic
4. Augmentation of the party wall
5. Closure of TEP and repeat TEP

SCARRING OF THE TEP :

Most often if the tract is not puncture but is made using a vertical incision. Patient complains of periprosthetic leakage from the same site.

INFECTION OF THE TEP TRACT :

Consider broad spectrum antibiotics and allow proper fitting VP for a swollen tract. Downsize if needed. Do not remove VP , it can cause permanent closure of the tract.

HYPERTROPHY OF THE TEP :

ANTERIOR HYPERTROPHY :

Due to overgrowth of the tracheal flange. seen in patients who require a tracheal cannula.

TREATMENT : remove the hypertrophic tissue and do stomatoplasty

POSTERIOR HYPERTROPHY :

Not easily noticed .Deterioration of their voice or blood on the brush while cleaning inside the VP.

TREATMENT : insert longer VP

PULMONARY REHABILITATION :

The disconnection of the upper and lower airways has repercussions for the conditioning – warming, humidifying and filtering of inhaled air . Breathing resistance also lost. Involuntary coughing, excessive phlegm production, forced expectoration and dyspnoea also occur to prevent the complication of pulmonary problems .Heat and moisture exchange systems plays a role . The HME placed over the tracheostoma that all inspired air passed through the device. It protects the trachea and the lower airway from drying and cooling and considerably reduces the burden of air conditioning of the lower tract. It also gives resistance to airflow.

OLFACTORY REHABILITATION :

Detioration of the sense of smell seems an inevitable . Consequences of TL breath through a tracheostoma in the neck and thereby absence of nasal flow. Odour molecules are no longer passively reaching the olfactory epithelium and patients are effectively anosmic despite the intact olfactory epithelium.

Rehabilitation technique for olfaction : polite yawn technique

HARRISSON ROBILLARD SHULTZ SCORE :

Each patient received voice prostheses rehabilitation training by a speech therapist for 2 weeks after voice prostheses placement that observed for about 6 months .

Functional voice outcome were recorded this score . This scale defines success by three parameters scored on 1 – 5 points scale : Use (degree to which tracheoesophageal speech is used as the main means of communication), Quality (the ease of voice production and its effect on intelligibility) and Care (degree of patient independence from professional aid for maintenance of the fistula and the prosthesis). An overall score of 12 or higher is considered successful VP rehabilitation .

VOICE HANDICAP INDEX :

The impact of voice impairment in the patients life was assessed with Voice Handicap Index . All patients administered the questionnaire and measure called the voice handicap index was calculated. The measure refers to the total sum obtained (minimum of 0 and maximum of 120) when voice handicap score is administered.

REVIEW OF LITERATURE

Johann Nepomuk czermak in 1859 developed **an artificial larynx** and laid the foundation for voice prosthesis. In 1869 , he developed artificial larynx in 18 years old complete laryngeal stenosis patient.

Vincenz Von Czerny in 1870 done laryngectomy in dogs and concluded that total laryngectomy feasible in humans . J.leiter developed a cannula and studied it effectiveness in dogs. **A.A.M. Raynaud(1848)** described method of **esophageal speech**.

Christian Albert Theodar Billroth in 1829 to 1894 credited with first successful **laryngectomy in human patient**.

Gussenbauer in 1874 , first documented successful laryngectomy and **internal prosthesis for voice restoration**

David Foulis in 1877 described an internal voice prosthesis that was based on ideas of Gussenbauer.

Victor Von bruns in 1878 introduced internal laryngeal prosthesis made up of new silver.

Paul Von Bruns in 1881 improved the ideas for voice prosthesis

Julius Wolff in 1892 made another internal VP in an attempt to improve prevention of crusting and improve voice quality.

In 1925, R.G.Brown devised internal voice prosthesis . Small metal pitch pipe that was attached to speculum. Speculum was placed into TEP and fixed to the neck using shield. This enables the patient to self insert the prosthesis and remove it before meals.

Guttman MR in 1932 described the case of laryngectomized patient and created an opening between trachea and oesophagus . This enabled the patient to produce a voice by occluding the tracheostoma with a finger.

R.T. Barton in 1965 described T shaped cannula enabled the patient to direct air into the oral space.

Asai et al in 1960 described 3 stage procedure.

Mc Grail and Oldfield in 1971 performed single stage procedure and in 1980 , one stage technique involving use of TE wall mucosa in order to create a fistula between trachea and esophagus.

S.taub in 1972 discovered novel external voice prosthesis under the name of voice bak.

E.Mozolewski in 1972 discovered first modern voice prosthesis.

Eric D. Blom in 1978 introduced **Duck bill valves**, a first non indwelling Voice prosthesis and modified by adding tracheal flange.

Hilgers and Schouwenburg (1988) discovered first generation provox indwelling prostheses .In 2003 , Provox actualy coated with Teflon to

prevent biofilm growth and fitted with magnet to close the valve mechanism. In 2010, provox prosthesis was further modified in order to reduce airflow resistance and optimize the fit of the prosthesis.

C Debry(2012) described development of **totally implantable VP** that allows the tracheostoma closed in laryngectomized patients.

Statistical analysis and interpretations:

The study subjects were classified according to their TEP and compared between them in respect of their continuous variables by independent student “t” test. The categorical variables were analysed and interpreted by χ^2 (Chi-square test. The above statistical procedures were under taken with the help of the statistically package namely IBMSPSS statistics-20. The P-values less than or equal ($P \leq 0.05$) were treated as statistically significant.

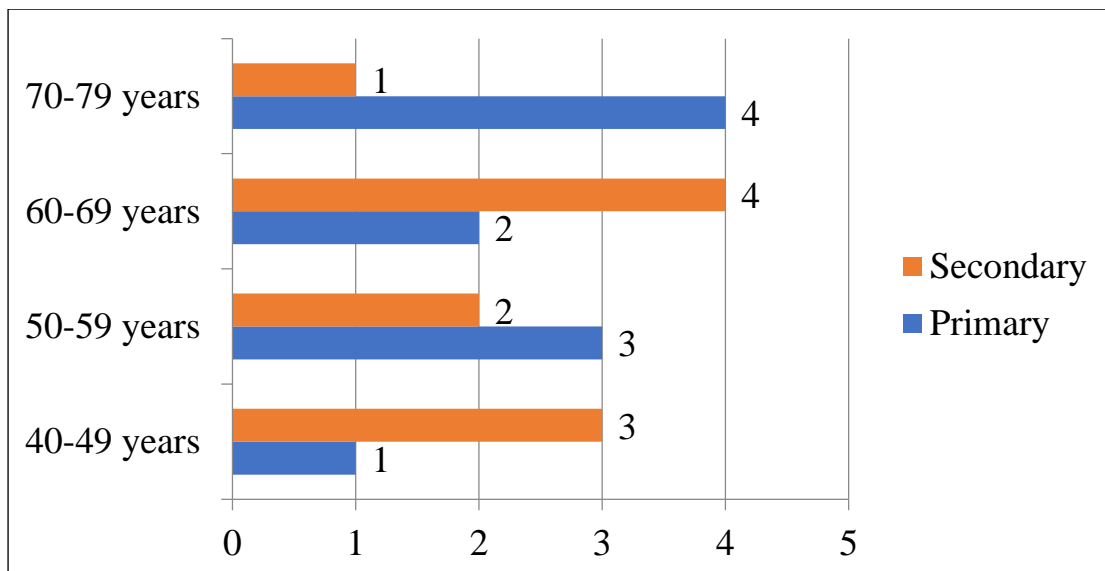
RESULTS AND OBSERVATION

1. COMPARISON OF AGE BETWEEN THE TWO GROUPS:

Age group (years)	Primary TEP		Secondary TEP	
	Frequency	%	Frequency	%
40-49	1	10.0	3	30.0
50-59	3	30.0	2	20.0
60-69	2	20.0	4	40.0
70-79	4	40.0	1	10.0
Total	10	100.0	10	100.0
Mean± SD	64.2±9.8		54.5±10.8	
Significance	“t”=2.108,df=18, P=0.049.			

The table-1 states the age of the two groups. The mean age of the primary group was 64.2±9.8 years and secondary group was 54.5±10.8. The difference of age between the two group was statistically significant (P<0.05).

Fig-1: Comparison of age between the two TEP:

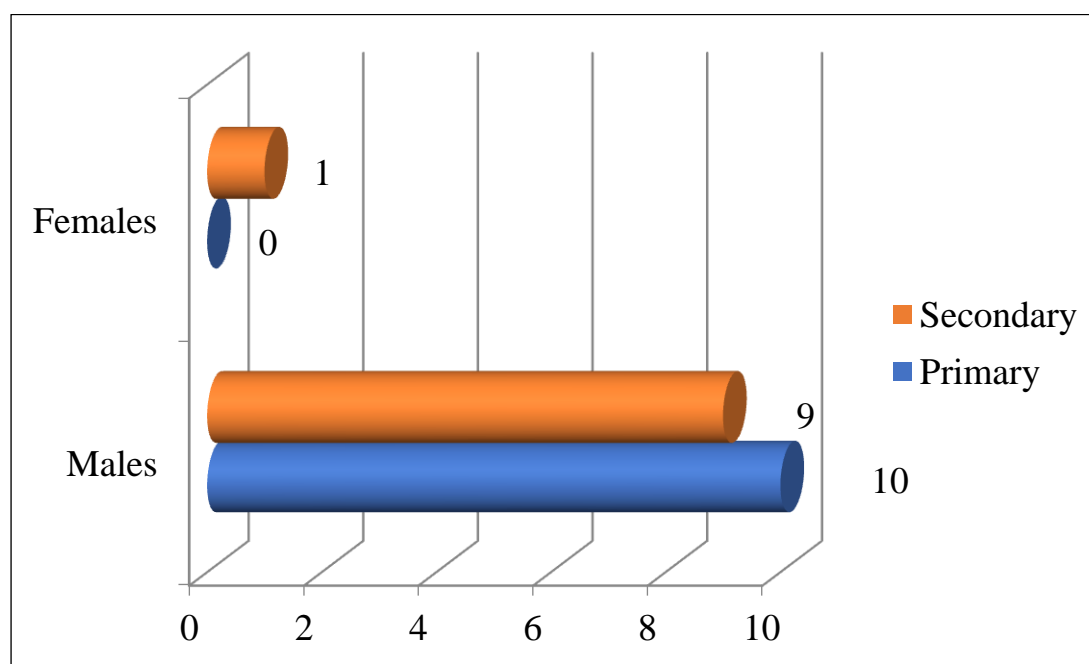


2. COMPARISON OF GENDER BETWEEN THE TWO GROUPS:

Gender	Primary TEP		Secondary TEP		Total		Significance
	No	%	No	%	No	%	
Males	10	100.0	9	90.0	19	95.0	$\chi^2=1.053$ df=1 P=0.305
Females	0	0.0	1	10.0	1	5.0	
Total	10	100.0	10	100.0	20.	100.0	

The males were 100% in primary TEP and 90% of males and 10% of females in secondary TEP. The difference between the two groups was not statistically significant ($P>0.05$).

Fig-2: Gender of the two groups:

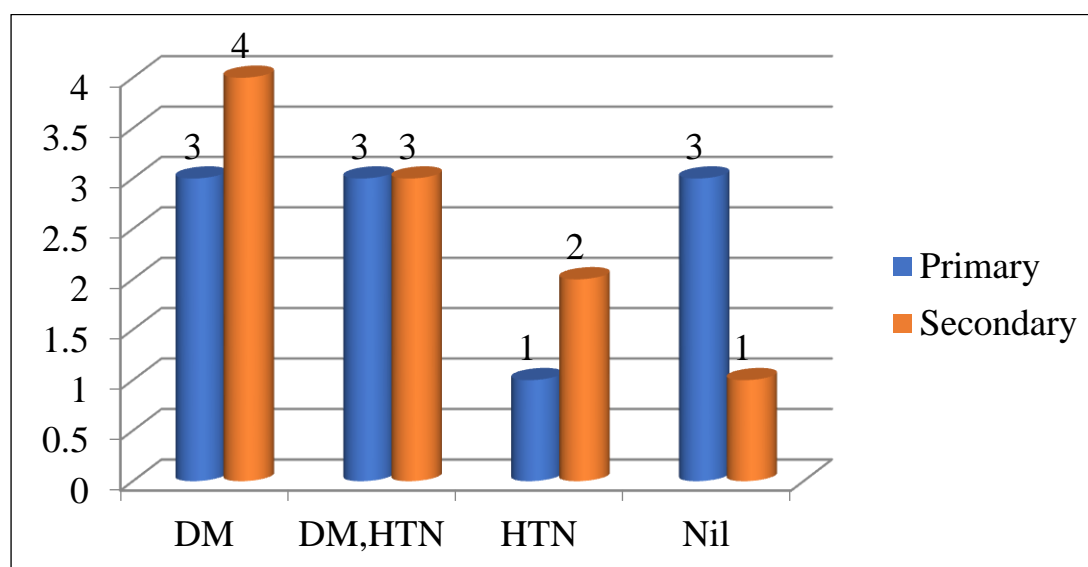


3.COMPARISON OF COMORBITY BETWEEN TWO GROUPS :

Co-morbidity	Primary TEP		Secondary TEP		Total		Significance
	No	%	No	%	No	%	
DM	3	30.0	4	40.0	7	35.0	$\chi^2=1.476$ df=1 P=0.688
DM,HTN	3	30.0	3	30.0	6	30.0	
HTN	1	10.0	2	20.0	3	15.0	
Nil	3	30.0	1	10.0	4	20.0	
Total	10	100.0	10	100.0	20	100.0	

Patients with diabetes and hypertension undergone tracheoesophageal puncture with VP were 60 % and 90 % in primary and secondary TEP respectively. The co-morbidity between the two groups was not statistically significant ($P>0.05$)

Fig-3: Co-morbidity between the two groups:

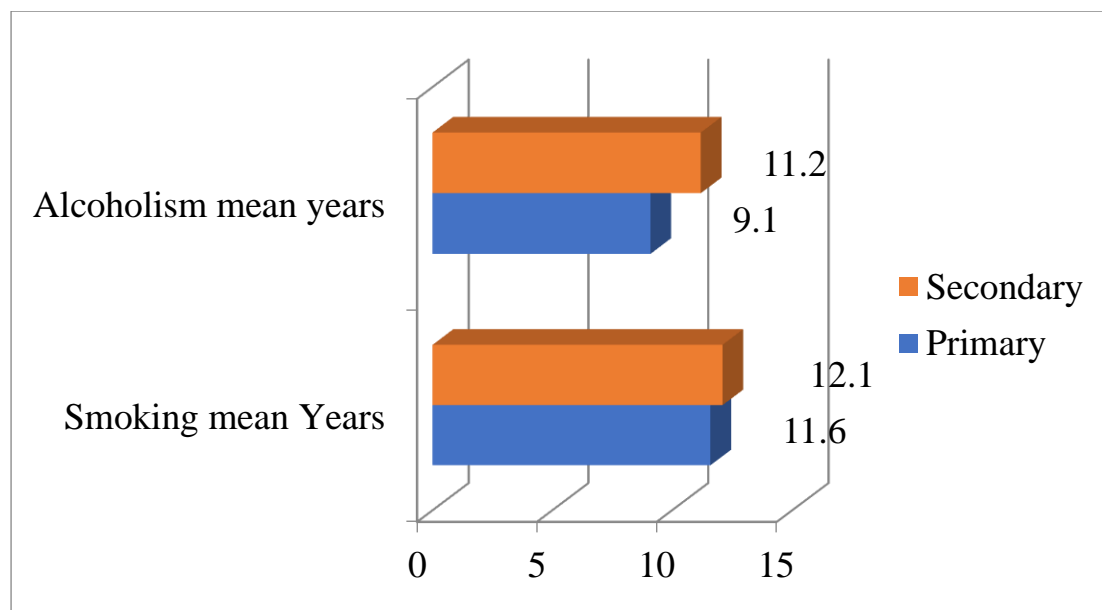


**COMPARISON OF SMOKING AND ALCOHOLISM BETWEEN
THE TWO GROUPS :**

Variable (years)	Primary		Secondary		Difference b/w means	“t”	df	Significance
	Mean	SD	Mean	SD				
Smoking	11.6	8.5	12.1	8.9	0.5	0.128	18	P=0.899
Alcohol	9.1	10.9	11.2	10.9	2.1	0.432	18	P=0.671

The table-4 states the comparison between the two groups in respect of their personal histories like smokers and alcoholism. The mean years of smokers in both groups were 11.6±12.1 years and 12.1±8.9 years respectively . The difference between them were not statistically significant (P>0.05). The mean years of alcoholism of both groups were 9.1±10.9 years and 11.2±10.9 years. The difference between them were not statistically significant (P>0.05).

Fig-4: Comparison of smoking and alcoholism between the two groups:



COMPARISON OF TUMOR SITE BETWEEN THE TWO GROUPS

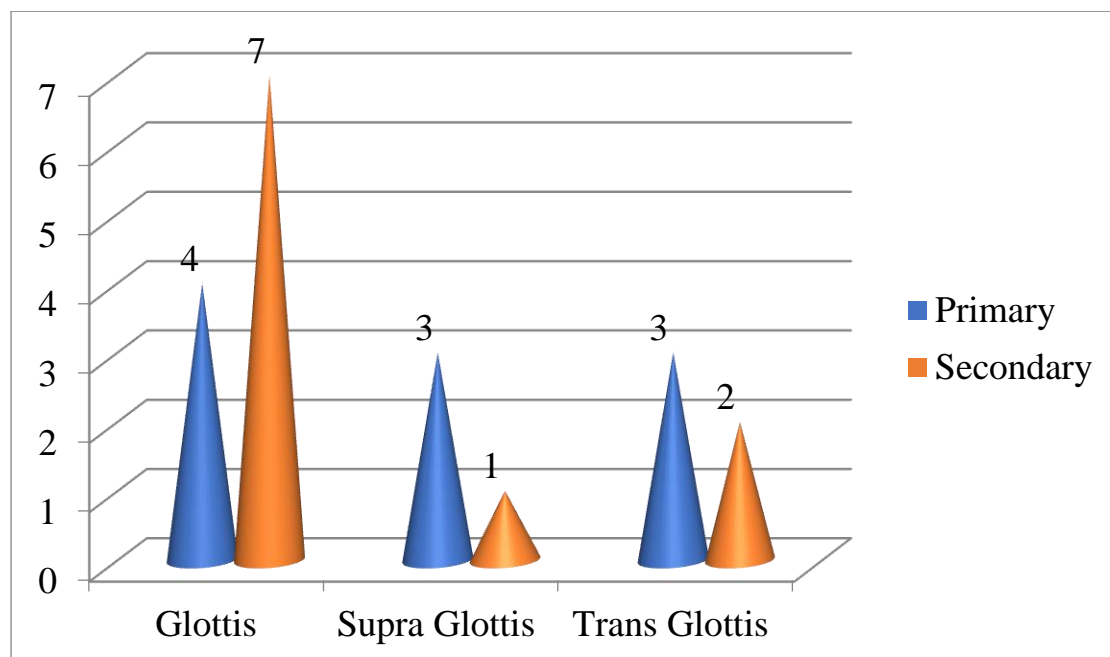
Tumor Site	Primary		Secondary		Total		Significance
	No	%	No	%	No	%	
Glottis	4	40.0	7	70.0	11	55.0	$\chi^2=2.018$ df=2 P=0.365
Supra Glottis	3	30.0	1	10.	4	20.0	
Trans Glottis	3	30.0	2	20.0	5	25.0	
Total	10	100.0	10	100.0	20	100.0	

The table-5 states the comparison of tumor sites of both groups. In my study , the most common tumor site who undergone primary TEP was Glottic tumor(40 %) followed by equal distribution of supraglottis(30%) and transglottis(30%).

The most common tumor site who undergone secondary TEP was glottis (70%).

Sites of both groups were not statistically significant ($P>0.05$).

Fig-5: Comparison tumor sites of the two groups:

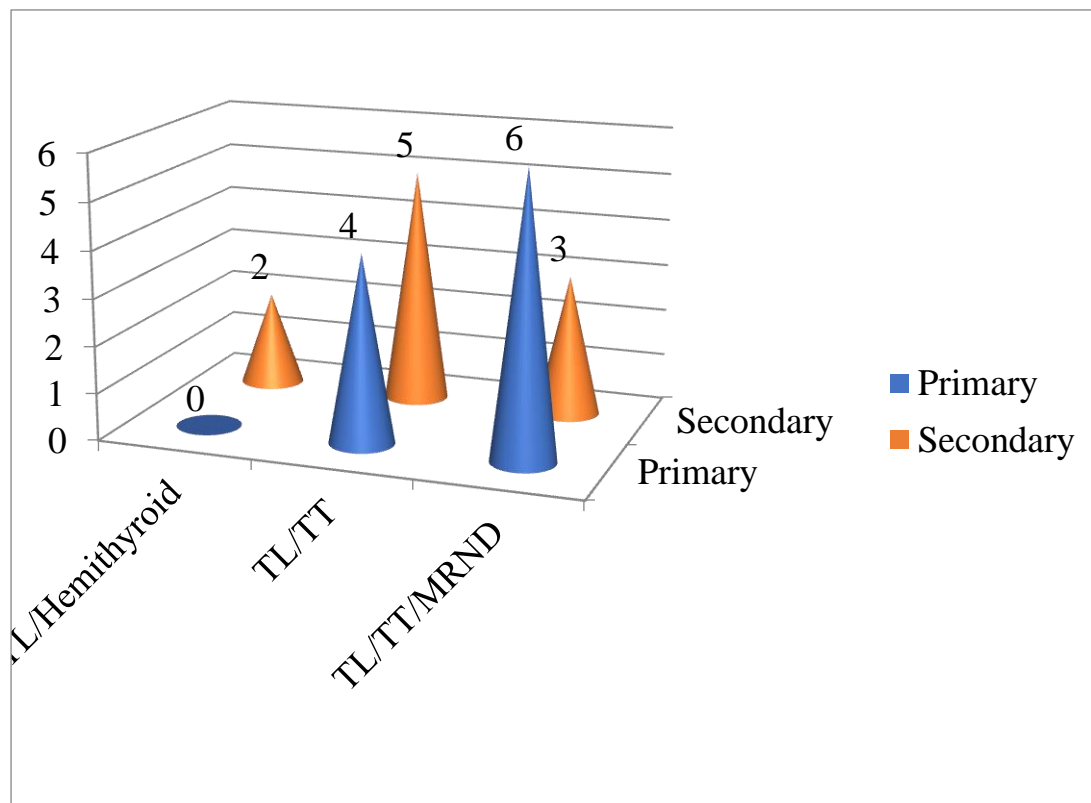


COMPARISON OF TYPE OF SURGERY BETWEEN THE TWO GROUPS:

Type of surgery	Primary		Secondary		Total		Significance
	No	%	No	%	No	%	
TL/Hemithyroid	0	0.0	2	20.0	2	10.0	$\chi^2=3.111$ df=2 P=0.211
TL/TT	4	40.0	5	50.0	9	45.0	
TL/TT/MRND	6	60.0	3	30.0	9	45.0	
Total	10	100.0	10	100.0	20	100.0	

In primary TEP , most of the patient undergone TL / TT / MRND (60%) and in secondary TEP were TL / TT (50%) .The type of surgeries between the two groups were not statistically significant($P>0.05$).

Fig-6: Comparison of type of surgery:

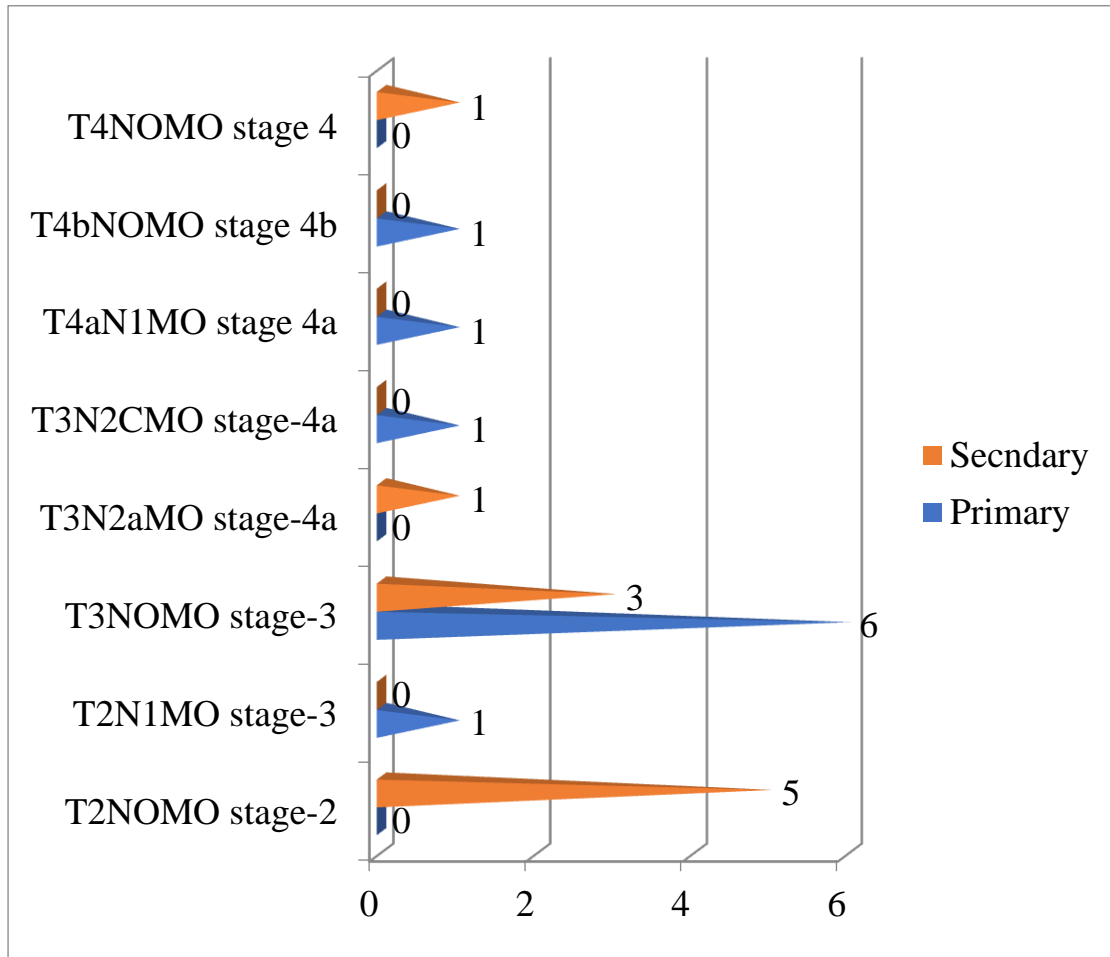


COMPARISON OF STAGE OF DISEASE BETWEEN THE TWO GROUPS :

Stage of diseases	Primary		Secondary		Significance
	No	%	No	%	
T2N0M0 stage-2	0	0.0	5	50.0	$\chi^2=12.000$ df=7 P=0.101
T2N1M0 stage-3	1	10.0	0	0.0	
T3N0M0 stage-3	6	60.0	3	30.0	
T3N2aM0 stage-4a	0	0.0	1	10.0	
T3N2CM0 stage-4a	1	10.0	0	0.0	
T4aN1M0 stage 4a	1	10.0	0	0.0	
T4bN0M0 stage 4b	1	10.0	0	0.0	
T4N0M0 stage 4	0	0.0	1	10.0	
Total	10	100.0	10	100.0	

The table-7 states the comparison of stages of diseases between the two groups. The patients who undergone laryngectomy with primary TEP were stage 3 and in secondary TEP were stage 2. The stages of diseases were not statistically significantly differed between the two groups (P>0.05).

Fig-7: Comparison of stages of diseases between the two groups:

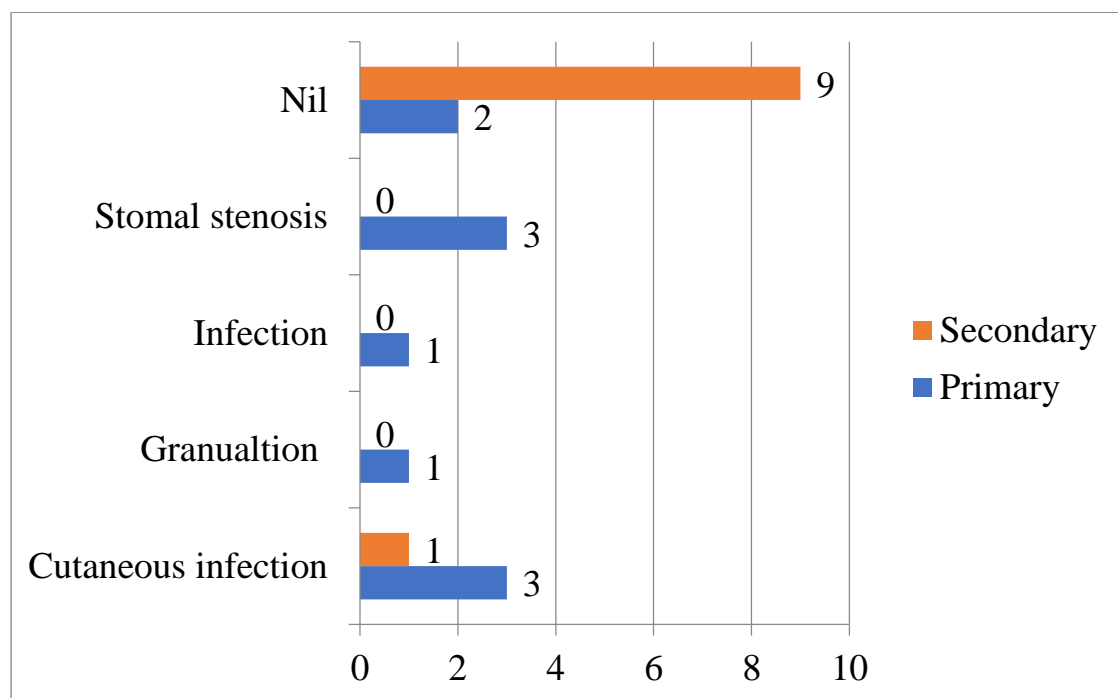


COMPARISON OF SURGICAL COMPLICATION BETWEEN THE TWO GROUPS :

Surgical complications	Primary		Secondary		Significance
	No	%	No	%	
Cutaneous Infection	3	30.0	1	10.0	$\chi^2=10.455$ df=4 P=0.033
Granulation	1	10.0	0	0.0	
Infection	1	10.0	0	0.0	
Stomal stenosis	3	30.0	0	0.0	
Nil	2	20.0	9	90.0	
Total	10	100.0	10	100.0	

The table-8 states the comparison of surgical complications: The surgical complications 80% and 10% in primary and secondary complication respectively . The surgical complications between the two groups were statistically significant (P<0.05)

Fig:8 : Comparison of surgical complications between the two groups:

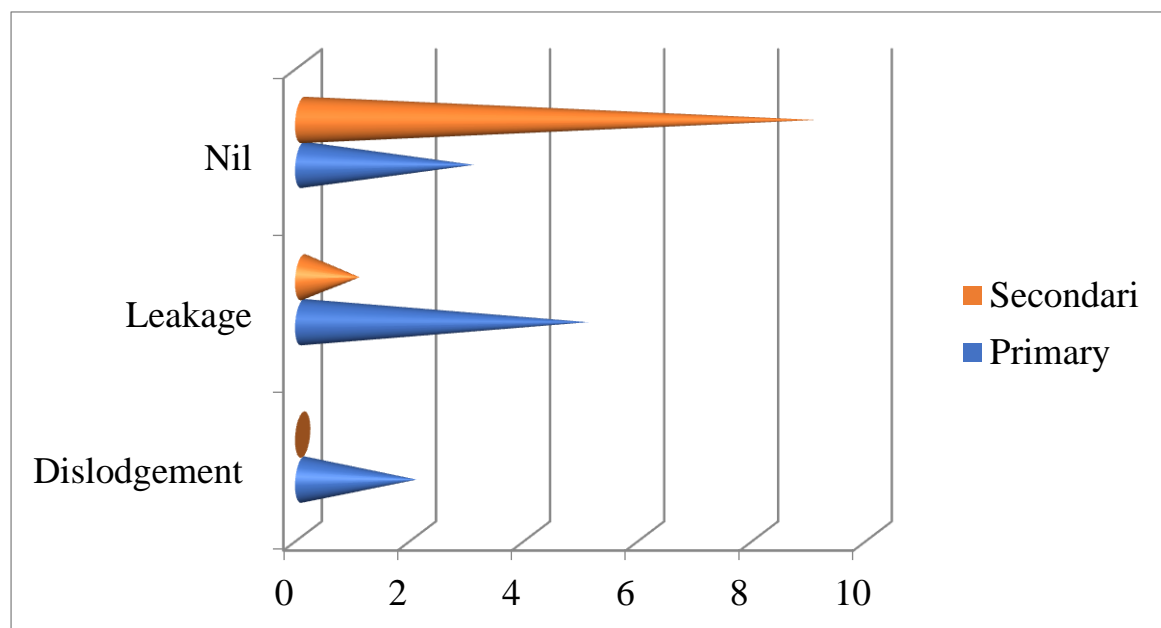


COMPARISON OF PROSTHETIC COMPLICATION BETWEEN THE TWO GROUPS:

Prosthetic complications	Primary		Secondary		Significance
	No	%	No	%	
Dislodgement	2	20.0	0	0.0	$\chi^2=7.667$ df=2 P=0.022
Leakage	5	50.0	1	10.0	
Nil	3	30.0	9	90.0	
Total	10	100.0	10	100.0	

The table-9 compares the Prosthetic complications between the two groups. The prosthetic complications are comparatively more in primary TEP (70 %) than secondary TEP (10 %). The Prosthetic complications were statistically significantly differed (P<0.05).

Fig-9: Comparison of Prosthetic complications between the two groups:



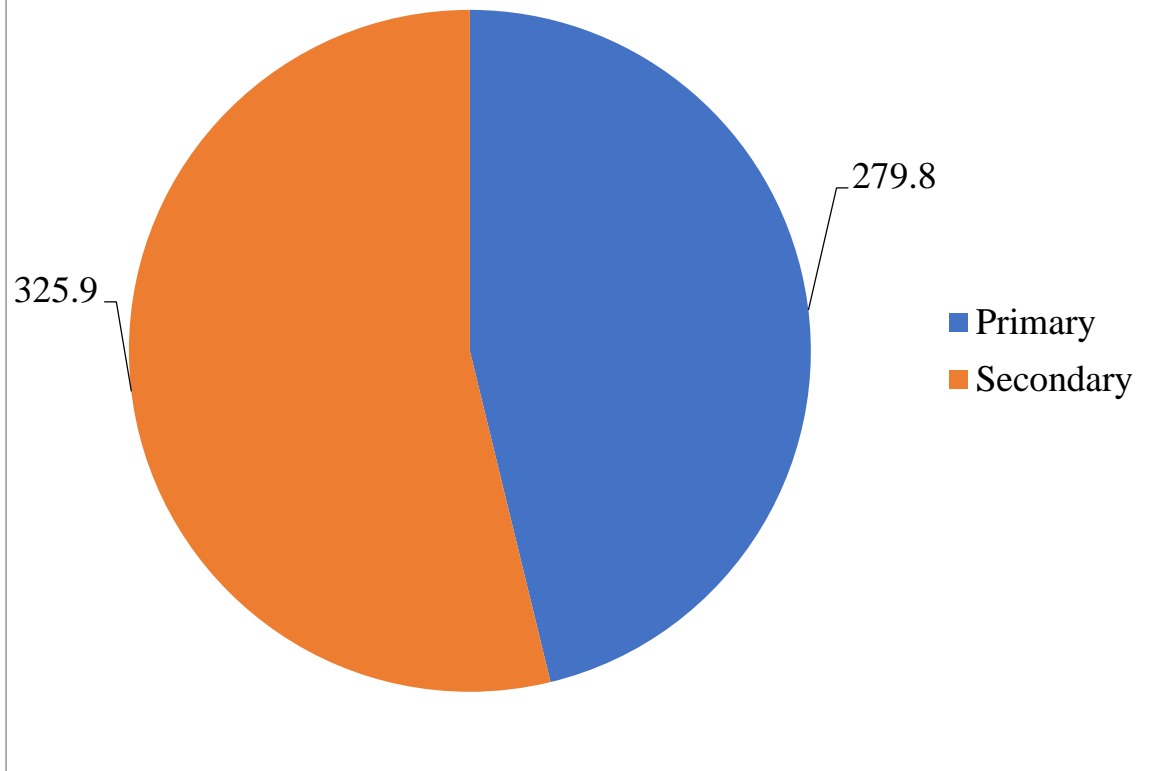
COMAPRISON OF VP LIFE TIME BETWEEN THE TWO GROUPS:

VP life time days	Primary		Secondary	
	Frequency	%	Frequency	%
100-200	2	20.0	1	10.0
200-300	4	40.0	3	30.0
300-400	4	40.0	3	30.0
400-500	0	0.0	3	30.0
Total	10	100.0	10	100.0
Mean± SD	279.8±85.2		325.9±96.0	
Significance	“t”=1.136, df=18, P=0.271.			

The table-10 compares the VP life time days. The mean days of both groups were 279.8±85.2 days and 325.9±96.0 days in primary and secondary TEP respectively. with interval range of 102 to 496 days . The mean device life time of voice prosthesis was 302 days and median device lifetime was 298 days. The Secondary TEP has more VP lifetime than primary TEP. The difference between the two group was not statistically significant (P>0.05)

Fig-10: comparison of means of VP life time days:

Mean VP life time

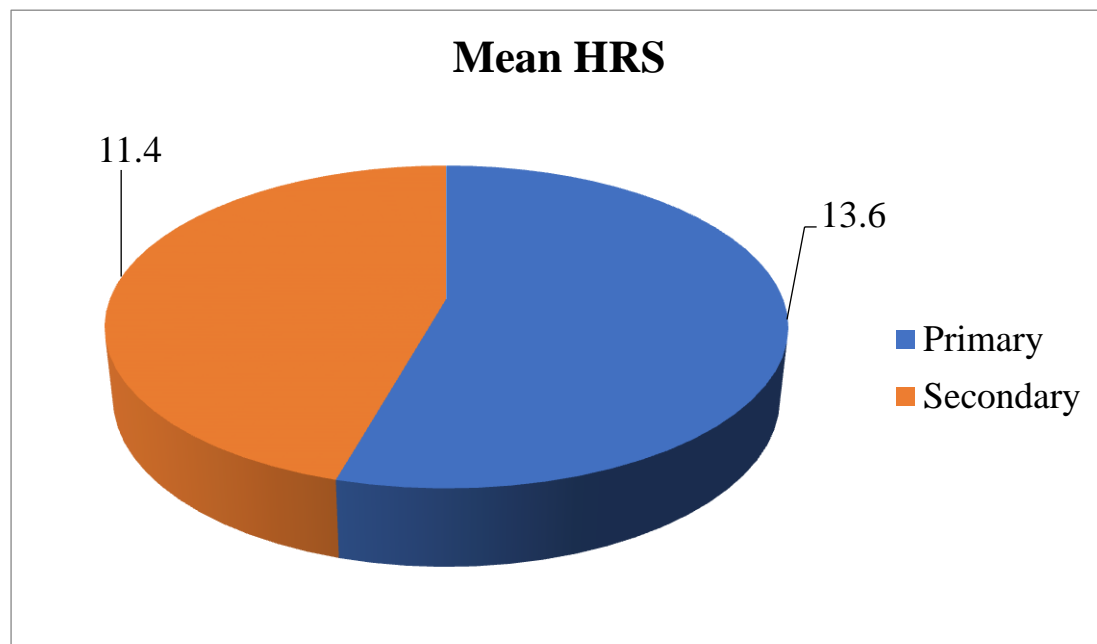


COMPARISON OF HRS RATING SCALE BETWEEN TWO GROUPS

HRS score	Primary		Secondary	
	Frequency	%	Frequency	%
10-15	7	70.0	10	100.0
15-20	3	30.0	0	0.0
Total	10	100.0	10	100.0
Mean± SD	13.6±1.8		11.4±1.6	
Significance	“t”=3.440, df=18, P=0.003			

The table-11: compares the HRS between the two groups. The mean of the both groups were 13.6±1.8 and 11.4±1.6 in primary and secondary TEP respectively. The success rate of voice prosthesis were 94 % and 77 % in primary and secondary TEP. The difference between them was statistically highly significant (P<0.01).

Fig-11:

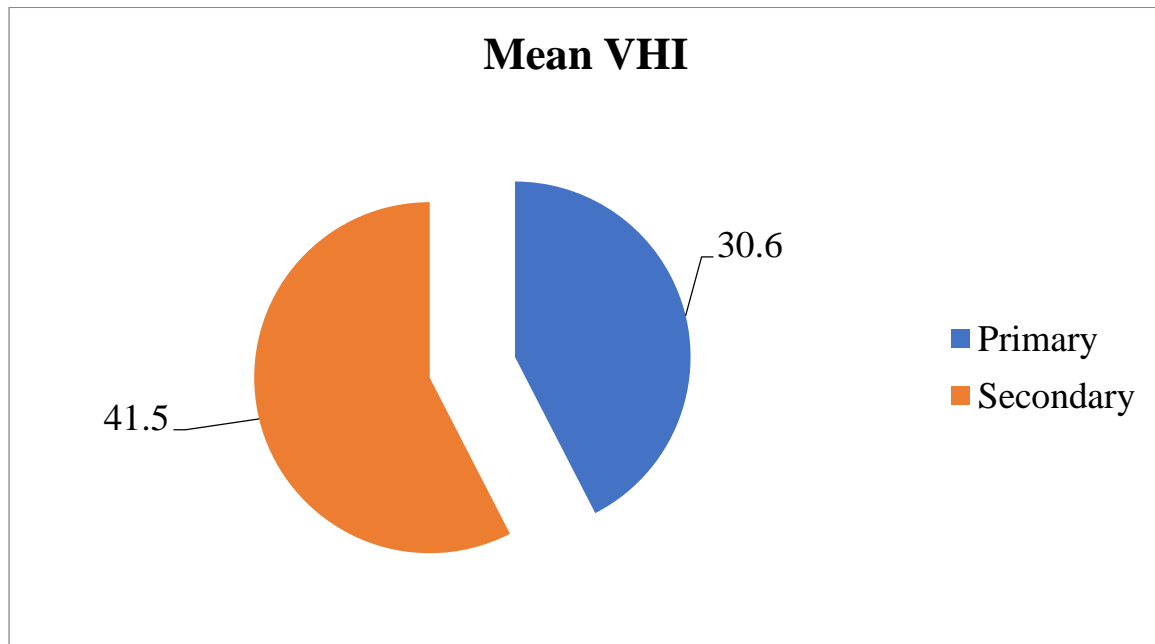


COMPARISON OF VHI SCORE BETWEEN THE TWO GROUPS:

VHI score	Primary		Secondary	
	Frequency	%	Frequency	%
20-30	7	70.0	0	0.0
30-40	3	30.0	6	60.0
40-50	0	0.0	1	10.0
50-60	0	0.0	3	30.0
Total	10	100.0	10	100.0
Mean± SD	30.6±6.0		41.5±10.7	
Significance	“t”=2.809, df=18, P=0.012			

The table-12 compares the VHI score between the primary and secondary groups. The mean of the primary subjects was 30.6±6.0 and the same of the secondary subjects was 41.5±10.7 . Increase in voice handicap index seen in secondary TEP . The difference between the two groups was statistically significant (P<0.01).

Fig-12: Comparison of VHI score between the two groups:



DISCUSSION

AGE:

During my study period , the age wise distribution of male to female patients range from 40 to 75 years. The most common age group in our study have undergone primary and secondary tracheoesophageal puncture are 64.2 +/- 9.8 years and 54.5 +/- 10.8 years respectively. The difference between the two age group was statistically significant.

According to Ignazio La Mantia et al , age wise distribution for primary and secondary tracheoesophageal puncture was 56.4 +/- 4.11 years and 63.7 +/- 3.22 years respectively.

According to Heather . M. starmer et al , the age distribution for primary and secondary TEP was 18.5 % and 66% respectively.

GENDER:

In our study , gender distribution of males are 100 % and no females in primary TEP and males are 90% and females are 10 % in secondary TEP.

Similarly Ignazio La mantia et al showed that in primary TEP (male 81.7 % and female 18.3 %) and in secondary TEP (male 82% and female 18%) respectively.

COMPLICATIONS OF TEP :

In our study , 50 % and 30 % of surgical complication in primary and secondary TEP respectively.

Also , 30 % and 60 % of prosthetic complication in primary and secondary TEP respectively.

We verified that in primary TEP surgical related complication are more in line with other published studies.

In secondary TEP , prosthetic related complications are more than primary TEP, according to our study.

According to Ignazio La Mantia et al , surgical related complication and prosthetic related complication are more in primary TEP than secondary TEP. The difference were not statistically significant .

According to Cheng et al , 68 patients who undergone total laryngectomy and tracheoesophageal puncture did not find any significant difference with respect to complication between primary and secondary TEP respectively.

According to Dayangku et al , 24 patients subjected to primary and secondary TEP . They did not find any significant difference .

According to Jose carlos barauno neto et al , and Emerick et al , primary TEP has more surgical complications than secondary TEP .

According to Boscolo rizzo et al , both primary and secondary TEP are equally safe.

VP LIFETIME :

Blom singer voice prosthesis implanted in our study were replaced with a interval range from 102 to 496 days with mean lifetime of 302 days. The mean duration are 279.8 +/- 85.2 days and 325.9 +/- 96 days in primary and secondary TEP respectively which is statistically insignificant.

In Heather . M . Stammer , mean VP life time are 22. 8 months and 15. 2 months in primary and secondary TEP respectively.

In Ignazio La Mantia et al , prosthesis implanted in their study were replaced in interval range from 98 to 196 days with mean lifetime of 171 days and the median lifetime was 166 days.

According to Sara cruz et al , 83 patients undergone in studies with mean device life time of voice prosthesis is 9.8 months in both primary and secondary TEP.

In Michel .A. Holtz et al, mean lifetime of voice prosthesis is 4.2 months

In Alper Yenigun et al , mean duration was 47.8 +/- 54 days and VP life time was 24 months.

HRS RATING SCALE :

In our study , HRS rating scale was used for assessment of voice prosthesis rehabilitation 94 % of patients achieved functional tracheoesophageal speech in primary TEP and 77 % in secondary TEP .we found a slight tendency for a higher success rate in primary TEP and statistically significant.

But in contrast with a series reported by cheng et al who found that two procedures were unequally successful in restoring voice (77.8 % for primary TEP vs 50 % for secondary TEP)

Study done by Ignazio et al , success rate of functional tracheoesophageal speech are 87 % and 76% in primary and secondary TEP respectively .

Study done by A.Serra et al , success rate of functional voice outcome after voice prosthesis are 78 % and 86 % in primary and secondary TEP respectively.

Study done by Alper Yenigun et al , 27 patients undergone in their studies in which success rate of functional tracheoesophageal speech are 65.9 % and 91 % in primary and secondary TEP respectively.

Similarly , a study done by Carlos T. Chone et al , success rate of voice rehabilitation with VP was 94% and in primary TEP was 97 % and 78 % in secondary TEP.

VHI SCORING :

In our study , overall total VHI score in voice prostheses was 32.15 and all patients achieved excellent voice quality. The mean score are 30.6 and 41.5 in primary and secondary TEP respectively .The increase in Voice handicap index seen in secondary TEP than primary TEP. Most of the patient have moderate voice handicap index in our study.

Study done by Sara cruz et al ,the mean total VHI score was 37.5 and 50 % of patients achieved satisfactory voice quality.

Study done by Maria Schuster et al , 20 laryngectomized patient using voice prosthesis and their VHI was 45.5 +/- 24.1 .

Study done by Eryl evans et al , mean total VHI score was 44. 7

CONCLUSION

Tracheoesophageal puncture is an effective method of choice for voice rehabilitation in laryngectomized patient. The percentage of successful voice rehabilitation, device lifetime and surgical and prosthetic complications between primary and secondary TEP are comparable . The rate of surgical complications are slightly high in primary TEP than secondary TEP which was statistically significant .

The increase in rate of voice prosthesis lifetime was seen in secondary TEP because of second surgery after salvage surgery with postoperative radiotherapy and decrease in surgical and prosthetic complications and also increase in rate of complications diminish the voice prosthesis life time in primary TEP but the rate of percentage of successful functional voice outcome are comparatively more in primary TEP. Effective surgical restoration with prosthetic valve by TEP and careful selection of patients with good hand dexterity, motivation effective speech therapy with capacity to learn quick leads to satisfactory functional voice outcome for a high rate of successful voice rehabilitation in most laryngectomized patients.

CLINICAL IMAGES



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PROFORMA

NAME:

AGE/SEX:

IP NO :

DATE OF SURGERY:

CHIEF COMPLAINTS:

PERSONAL HISTORY :

TUMOR SITE :

STAGE OF DISEASE:

TYPE OF SURGERY :

RADIOTHERAPY :

TYPE OF TRACHEOESOPHAGEAL PUNCTURE :

TYPE OF PROSTHESIS:

REPLACEMENT OF PROSTHESIS;

COMPLICATIONS OF TRACHEOESOPHAGEAL PUNCTURE:

POSTOP FOLLOWUP

THE HARRISON ROBILLARD SCULTZ TEP RATING SCALE

The Harrison–Robillard-Shultz TEP Rating Scale							
Name: _____				Date of TEP: _____			
Date	Months Post TEP	Rating Point	Use	Quality	Care	Overall	Success or Failure
_____	_____	0-11 wk: Immediate	___	___	___	___	___
_____	_____	0-11 mo: Short Term	___	___	___	___	___
_____	_____	>1 y: Long Term	___	___	___	___	___
Reason for discontinued use of tracheoesophageal speech: _____							Date: _____
<p>A. Use The degree of use of tracheoesophageal speech.</p> <ol style="list-style-type: none"> 1. Never uses tracheoesophageal speech (0%). 2. Uses tracheoesophageal speech less than 50% of the time. 3. Uses tracheoesophageal speech 50% to 80% of communicative attempts. 4. Uses tracheoesophageal speech manually occluded as main means of communication. 5. Uses tracheoesophageal speech with tracheostoma valve as main means of communication. <p>B. Quality The ease of production and intelligibility of speech as determined by fluency and ability to occlude.</p> <ol style="list-style-type: none"> 1. Unable to get sound; no use of pulmonary air for speech. 2. Voice is too strained or too breathy to permit functional use in conversation (may interfere with intelligibility); includes whispered speech. 3. Stoma, more often than not, is poorly occluded with resultant air escape that interferes with intelligibility or is a distraction to the listener. 4. Voice is mildly stained or mildly breathy, but continuous use in conversation is possible; occlusion is generally good; speech is intelligible. 5. Voice is easily produced; occlusion is good; speech is intelligible. <p>C. Care Patient independence of medical or other health care professionals (includes speech/language pathologist, nurse, community worker) for 4 behaviors: (1) remove and insert prosthesis, (2) clean and sterilize prosthesis, (3) recognize problems and seek help immediately if needed, and (4) order supplies.</p> <ol style="list-style-type: none"> 1. Unable to do any of the 4 behaviors. 2. Independent for any 1 of 4 behaviors. 3. Independent for any 2 of 4 behaviors. 4. Independent for any 3 of 4 behaviors. 5. Independent for all 4 behaviors. 							

Figure 1. The Harrison–Robillard-Shultz Tracheoesophageal Puncture (TEP)

VOICE

HANDICAP

INDEX

Part I-F (functional)

F1. My voice makes it difficult for people to hear me	0	1	2	3	4
F2. People have difficulty understanding me in a noisy room	0	1	2	3	4
F3. My family has difficulty hearing me when I call them throughout the house	0	1	2	3	4
F4. I use the phone less often than I would like to	0	1	2	3	4
F5. I tend to avoid groups of people because of my voice	0	1	2	3	4
F6. I speak with friends, neighbors, or relatives less often because of my voice	0	1	2	3	4
F7. People ask me to repeat myself when speaking face-to-face	0	1	2	3	4
F8. My voice difficulties restrict personal and social life	0	1	2	3	4
F9. I feel left out of conversations because of my voice	0	1	2	3	4
F10. My voice problem causes me to lose income	0	1	2	3	4

Part II-P (physical)

P1. I run out of air when I talk	0	1	2	3	4
P2. The sound of my voice varies throughout the day	0	1	2	3	4
P3. People ask, "What's wrong with your voice?"	0	1	2	3	4
P4. My voice sounds creaky and dry	0	1	2	3	4
P5. I feel as though I have to strain to produce voice	0	1	2	3	4
P6. The clarity of my voice is unpredictable	0	1	2	3	4
P7. I try to change my voice to sound different	0	1	2	3	4
P8. I use a great deal of effort to speak	0	1	2	3	4
P9. My voice is worse in the evening	0	1	2	3	4
P10. My voice "gives out" on me in the middle of speaking	0	1	2	3	4

Part III-E (emotional)

E1. I am tense when talking to others because of my voice	0	1	2	3	4
E2. People seem irritated with my voice	0	1	2	3	4
E3. I find other people don't understand my voice problem	0	1	2	3	4
E4. My voice problem upsets me	0	1	2	3	4
E5. I am less outgoing because of my voice problem	0	1	2	3	4
E6. My voice makes me feel handicapped	0	1	2	3	4
E7. I feel annoyed when people ask me to repeat	0	1	2	3	4
E8. I feel embarrassed when people ask me to repeat	0	1	2	3	4
E9. My voice makes me feel incompetent	0	1	2	3	4
E10. I am ashamed of my voice problem	0	1	2	3	4

FUNCTIONAL ;

PHYSICAL :

EMOTIONAL :

TOTAL:

PATIENT CONSENT FORM

Title of the Project : “A STUDY OF PRIMARY AND SECONDARY TRACHEOESOPHAGEAL VOICE PROSTHESES IN TOTAL LARYNGECTOMY“

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:

ஆராய்ச்சி தகவல் தாள்

ஆய்வு செய்யப்படும் தலைப்பு :

“A STUDY OF PRIMARY AND SECONDARY TRACHEOESOPHAGEAL
VOICE PROSTHESES IN TOTAL LARYNGECTOMY”

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 STUDY OF PRIMARY AND SECONDARY TRACHEOESOPHAGEAL
VOICE PROSTHESES IN TOTAL LARYNGECTOMY”

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.ABIRAMI C,
Post Graduate, MS ENT, second year,
Madras Medical College,
Chennai – 600 003.


Dear Dr. ABIRAMI C,

The Institutional Ethics Committee has considered your request and approved your study titled **“A STUDY OF PRIMARY AND SECONDARY TRACHEOESOPHAGEAL VOICE PROSTHESES IN TOTAL LARYNGECTOMY”- NO.14102020**. The following members of Ethics Committee were present in the meeting held on **21.10.2020** 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.Rema 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



Document Information

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S.NO	NAME	AGE/SEX	COMORBITTIE S	PERSONAL HISTORY	TUMOR SITE	DATE OF Sx	TYPE OF SURGERY	STAGE OF DISEASE	RADIOTHERAPY	TYPE OF TEP	TYPE OF PROSTHESIS	VP LIFETIME	SURGICAL COMPLICATION	PROSTHETIC COMPLICATION	HRS SCORE	VHI SCORE
1	NAGANATHAN	66/M	T2DM	smoker 15 yrs	Glottis	10/12/2012	TL / TT	T3N0M0 Stage 3	yes	primary	Blom singer	275 days	nil	leakage	12	28
2	SELVARAJ	58/ M	HTN	Smoker 20yrs	Glottis	12/21/2012	TL / TT	T3N0M0 Stage 3	yes	primary	Blom singer	196 days	cutaneous infection	nil	14	46
3	SAMUEL	41/M	T2DM	smoker 15yrs alcohol 8 yrs	Transglottis	7/19/2019	TL/TT/MRND	T3N0M0 Stage 3	Yes	secondary	Blom singer	404 days	nil	nil	12	24
4	SIVA	40/M	NIL	smoker 8 yrs Alcohol 10 yrs	Glottis	4/20/2013	TL/TT/MRND	T3N1M0 Stage 3	yes	secondary	Blom singer	496 days	nil	fungal infection	11	21
5	ABDUL RASHEED	48/M	HTN,DM	smoker 11 yrs Alcohol 10 yrs	Glottis	9/26/2019	TL/TT/MRND	T3N1M0 Stage 3	yes	secondary	Blom singer	368 days	nil	nil	12	52
6	KOVINDARAJ	46/M	HTN,DM	smoker 12 yrs Alcohol 10 yrs	Transglottis	2/20/2015	TL/TT/MRND	T3N2CM0 stage 4A	yes	primary	blom singer	292 days	infection	nil	10	43
7	CHANDRAN	52/M	HTN ,DM	smoker 12 yrs alcohol 5 yrs	supraglottis	3/23/2018	TL/TT	T2N0M0 stage 2	yes	secondary	Blom singer	309 days	granulation	nil	12	22
8	KANNIYAMMAL	62/F	HTN	NIL	Glottis	11/7/2017	TL/TT	T2N0M0 stage 2	yes	secondary	Blom singer	421 days	nil	leakage	13	27
9	VEERAPANDI	63/M	HTN	smoker 30yrs alcohol 30 yrs	Glottis	7/23/2018	TL/TT	T2N0M0 stage 2	Yes	secondary	Blom singer	185 days	nil	fungal infection	9	61
10	PERUMAL	72/M	DM	smoker 15 yrs alcohol 30 yrs	Glottis	2/13/2020	TL/TT/MRND	T2N1M0 stage 3	yes	primary	Blom singer	234 days	stomal stenosis	nil	12	45
11	SIVAKUMAR	72/M	DM	smoker 15 yrs alcohol 15 yrs	Transglottis	6/18/2014	TL/TT/MRND	T3N1M0 Stage 3	yes	primary	Blom singer	381 days	nil	nil	12	19
12	PALPANDI	61/M	T2DM	NIL	Glottis	8/16/2013	TL/Hemithyroidectomy	T3N2aM0 stage 4A	Yes	secondary	Blom singer	305 days	nil	dislodgement	11	23
13	SEETHARAMAN	61/M	T2DM	smoker 9 yrs alcohol 8 yrs	Glottis	7/11/2019	TL/Hemithyroidectomy	T2N0M0 stage 2	Yes	secondary	Blom singer	281 days	cutaneous infection	fungal infection	12	18
14	DASARATHAN	71/M	NIL	NIL	Transglottis	8/11/2019	TL/TT/MRND	T3N1M0 Stage 3	Yes	primary	Blom singer	366 days	nil	leakage	11	26
15	KUMAR	50/M	NIL	NIL	supraglottis	11/6/2019	TL/TT/MRND	T4aN1M0 stage 4a	yes	primary	Blom singer	352 days	granulation	nil	12	37
16	GOVINDHASAMY	75/M	DM	smoker18 yrs alcohol 31 yrs	Glottis	11/25/2019	TL/TT	T2N0M0 stage 2	yes	secondary	Blom singer	271 days	nil	nil	10	34
27	ELANGO VAN	52/M	DM, HTN	smoker 18 yrs alcohol 10 yrs	Transglottis	10/6/2020	TL/TT	T4N0M0 stage 4	yes	secondary	Blom singer	219 days	cutaneous infection	fungal infection	11	32
18	MANI	50/M	DM,HTN	smoker 21 yrs alcohol 21 yrs	supraglottis	5/5/2019	TL/TT	T3N0M0 Stage 3	yes	primary	Blom singer	281 days	nil	nil	11	26
19	DEKSHAN	65/M	DM.HTN	smoker 19 yrs alcohol 15 yrs	supraglottis	12/11/2019	TL/TT	T4bN0M0 stage 4b	yes	primary	Blom singer	319 days	stomal stenosis	NIL	12	28
20	GODHANDAN	72/M	NIL	NIL	Glottis	8/12/2021	TL/TT/MRND	T3N1M0 Stage 3	Yes	primary	Blom singer	102 days	nil	dislodgement	10	31