

**ASSESSMENT OF VOICE HANDICAP IN TOTAL
LARYNGECTOMY PATIENTS AT KENYATTA NATIONAL
HOSPITAL**

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**M.MED OTORHINOLARYNGOLOGY –HEAD AND NECK SURGERY
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the degree of Masters of Medicine in Otorhinolaryngology, Head and Neck
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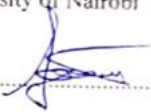
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ABBREVIATIONS

AJCC	-	American Joint Committee on Cancer
ENT	-	Ear Nose and Throat
ERC	-	Ethics and Research Committee
IMRT	-	Intensity Modulated Radiotherapy
KNH	-	Kenyatta National Hospital
PORT	-	Post-Operative Radiotherapy
QOL	-	Quality of Life
TEP	-	Tracheo-esophageal prosthesis
TES	-	Tracheo-esophageal speech
TL	-	Total Laryngectomy
UON	-	University of Nairobi
VHI	-	Voice Handicap Index
VRQL	-	Voice Related Quality of Life
WHO	-	World Health Organisation

ABSTRACT

Background

Surgical treatment for advanced laryngeal cancer entails total laryngectomy and an initial loss of voice. This has an expected negative impact on quality of life as patients lose their main mode of communication.

Objective: The study determined the level of voice handicap in laryngectomees.

Study Setting: The study was carried out at the Kenyatta National Hospital Ear Nose and Throat department clinic.

Methodology: This was a cross sectional descriptive study of 44 participants who had undergone total laryngectomy at least three months prior to the study and were recruited using convenience sampling technique. Participants completed a demographic and clinical data questionnaire and the Voice Handicap Index (VHI) Questionnaire. The VHI scores were calculated and correlation analysis was done with a statistical significance set at < 0.05 at 95% confidence interval. The independent sample T-test, Chi-square test and ANOVA test were used for this analysis.

Results: There were 44 participants in the study, 42(95.5%) were male and 2(4.5%) were female with an age range of 36 to 73 years. The total VHI mean was 17.95. Thirty-nine patients (89%) had a mild, while 2 (4.5%) had a moderate and 3 (6.9%) had a severe handicap. The total subdomain means were 7.9 for physical, 4.9 for functional and 5.2 for emotional domains. The majority of the patients 32 (72.7%) used whispering and had VHI mean of 19.6, while 10(22.7%) used an electrolarynx and had a VHI of 13.6 and 4.5% used tracheoesophageal prosthesis with a VHI of 13. There was no statistically significant difference in total or subdomain VHI across all three methods of rehabilitation.

Conclusion and Recommendations: This study demonstrates that most of our laryngectomees have a mild voice handicap. Even though it was not statistically significant, VHI was worse in those using whispering than those using electrolarynx and tracheoesophageal prosthesis. We recommend surgical voice rehabilitation to be used after laryngectomy as it is the gold standard and gives better handicap scores.

1.0 CHAPTER ONE: BACKGROUND

1.1 Introduction

The voice is the primary means of communication in our everyday life. It plays a role in communicating ideas while at the same time conveying biological and paralinguistic information. Social status, emotional state, personal traits and a person's origin can all be derived from the tone, pitch and accent of a speaker¹. Total laryngectomy results in an initial total loss of voice post operatively. Voice handicap assessment and appropriate voice rehabilitation can greatly improve quality of life (QOL) after total laryngectomy².

1.2 The Larynx and Carcinoma

In Sub Saharan Africa, carcinoma of the larynx is the third commonest head and neck squamous cell carcinoma with a prevalence of 4.5%³. Sandabe et al reported a prevalence of 20% of all head and neck cancers in Nigeria³. In Kenya, head and neck malignancies contribute 10.17% of all the malignancies with carcinoma of the larynx as the second most common head and neck cancer after nasopharyngeal carcinoma⁴. At KNH, the larynx was reported as the most common site amongst the head and neck cancers by Onyango and colleagues with a prevalence of 40%⁵. Carcinoma of the larynx is the major indication for total laryngectomy at KNH.

The larynx has three main functions, these are: respiration, protection of the airway during swallowing and production of voice⁶. It is found in the upper airway, just above the trachea and is divided into 3 sites anatomically namely the supraglottis, glottis and subglottis. Over 95% of malignancies of the larynx are squamous cell carcinomas⁷.

Malignancies can involve any of the subsites. Majority of tumours are glottic (50-60%), followed by supraglottic (30-40%) while subglottic carcinomas are uncommon ($\leq 5\%$)⁸. Carcinomas have negative implications on the voice causing mechanical obstruction to vocal cord movement, paralysis of the recurrent laryngeal nerve and blockage of the airway due to tumour bulk.

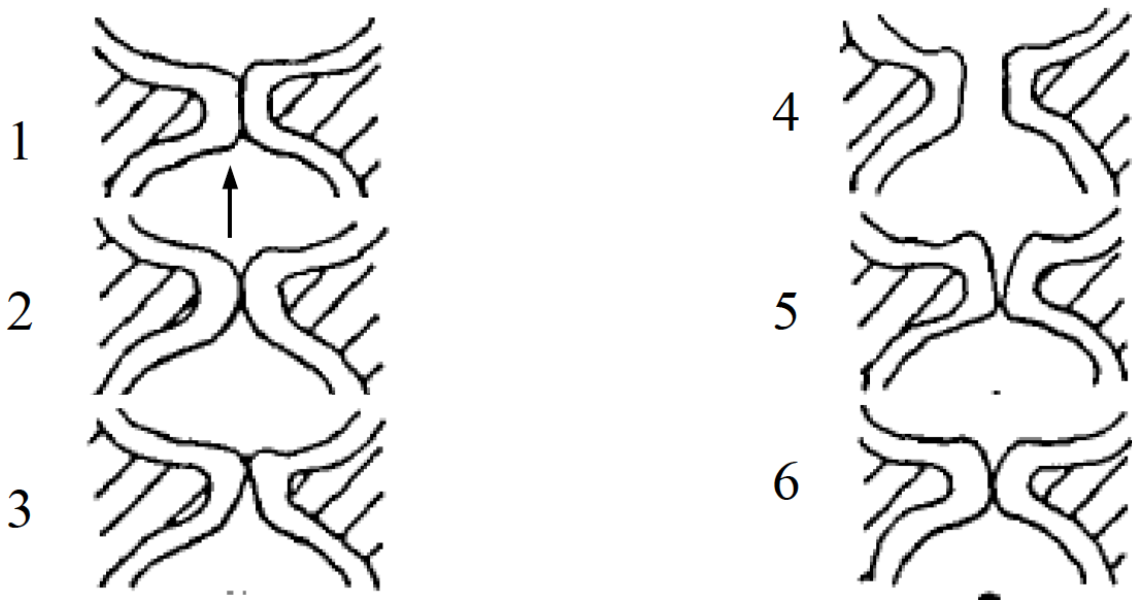
1.3 Voice Physiology

Voice and sound production depend on a complex interplay of the tissue properties of the lungs, larynx and the vocal tract which form an air system, vibratory system and a resonance (sound production) system respectively. The lungs, chest muscles, diaphragm, ribs and abdominal muscles comprise the air pressure system which provides and regulates air pressure and air flow. The glottic part of the larynx forms the vibratory system that serves to change air pressure to sound waves (buzzing sound). The third component of the system is the vocal tract that is

the tongue, lips, soft palate, pharynx and oral cavity and nasal cavity. This resonatory component modifies the buzzing sound to create specific output sounds ⁹. Voice production physiology has been explained by a number of theories, but the most widely accepted is the myoelastic-aerodynamic theory depicted in figure 1 below ⁹.

In this theory voice production begins with inhalation of air and glottic closure to position the vocal cords near the midline. Exhalation increases the subglottic pressure, forcing air between the paramedian vocal cords (frame 2). As air passes between the vocal cords, they vibrate and are displaced laterally (frame 4). The escape of air reduces the subglottic pressure again and the vocal cords return to the midline position (frame 6).

The forces that cause the return of vocal folds in the midline include the Bernoulli effect and the elastic recoil in the vocal cords. When vocal folds return to the midline the pressure builds up and the cycle begins again (frame 1). However, the vocal cords are not homogenous and opening starts from the inferomedial surface to the superior surface and by the time the superior surface opens, the inferior surface has already started closing (frame 3 and 5). Each vibratory cycle consists of three phases namely adduction, aerodynamic separation and elastic recoil.



Courtesy of Ladefoged and Johnson's (2015) A Course in Phonetics¹⁰

Figure 1: Showing the cross-sectional view of one vibratory cycle from frame 1 to 6

1.4 Carcinoma of the Larynx and Voice

The cardinal presenting symptom in carcinoma of the larynx is hoarseness of voice that is typically progressive, irreversible and results in total loss of voice even before intervention. The hoarseness is usually due to tumour infiltration, reduced mobility and/or fixation of the vocal cords, resulting in a less effective vibratory system and therefore hoarseness of voice ¹¹. Vocal cord action can also be hindered by tumour infiltration of the recurrent laryngeal nerve, which controls most of the structures involved in voice production. Voice changes may also be due to the mass effect of a supraglottic or glottic mass causing turbulence and reducing effectiveness of the resonatory system giving a breathy voice for example, and a reduction in the maximum phonatory time ^{1,7}.

Some of our late presenting patients also present with stridor due to the mass effect and/or infiltration of the recurrent laryngeal nerve and a tracheostomy is usually fashioned to relieve upper airway obstruction. Though effective in delivering air to the lungs for respiration, it bypasses the vibratory system and results in voice loss. The direct and indirect tumour effects and tracheostomy mean that there usually is vocal compromise even before definitive tumour intervention is initiated.

1.5 Laryngeal Cancer Treatment

Upon diagnosis of a malignancy, the initial aim of management is focused on removing cancer and improving survival. However, with recent advances in treatment outcomes and improved survival, morbidity is of increasing concern. The standard treatment for carcinoma of the larynx involves surgery, radiotherapy and chemotherapy in various combinations depending on The American Joint Committee on Cancer (AJCC) stage at diagnosis, patient preference and centre expertise¹². Most of the patients who present at the Kenyatta National Hospital present in late stage of the disease that is stage 3 or 4 ¹³.

The delay is mostly due to patient factors which are related to poverty and low level of education. In addition, early symptoms are dismissed as minor by both the patient and the primary health care providers before referral to a specialist centre¹³. Further investigation of otherwise serious symptoms is also limited by poor medical infrastructure that is in terms of both technology and personnel leaving otherwise serious symptoms un-investigated and deemed as trivial and frequently misdiagnosed as laryngitis, asthma or common cold.

In contrast to early disease which can be treated with a single modality, that is surgery or radiotherapy, advanced carcinoma of the larynx (stage 3 or 4) often requires a combination treatment protocol for optimum loco regional and distant control of disease. This often entails

total laryngectomy (TL) followed by post-operative radiotherapy (PORT) to control neck disease^{13,14}. In some cases where tumour extension is deemed inoperable or when a patient is not fit for surgery or the patient declines surgical option, chemotherapy and radiotherapy treatment modalities are used¹⁴.

1.5 Functional Changes Post Laryngectomy and Radiotherapy

At KNH, the most common combination employed is total laryngectomy followed by post-operative radiotherapy (PORT) to control microscopic disease locally. By removal of the whole vibratory apparatus, total laryngectomy has a more drastic and obvious effect on voice with subsequent aphonia. During total laryngectomy, all three regions of the larynx are removed.

The attachment of the pharyngeal constrictor muscles to the hyoid bone is resected, and sometimes parts of the pharynx including the pyriform sinus and post cricoid region may be resected together with the larynx depending on the extent of contiguous spread to the pharynx. Post total laryngectomy oesophageal speech requires a floppy neopharynx to vibrate and take the role of the vocal cords, thus pharyngeal resections and reconstructions that result in a tense or hypertonic neopharynx may hinder future oesophageal speech rehabilitation.

Radiotherapy induces pathophysiological changes on the vocal tract and the pharynx, including acute inflammation, altered microcirculation and fibrosis whose sequelae is chronic inflammation and oedema of the vocal tract and the remaining neo pharynx. This narrows and tenses the airway thus reducing effectiveness of the air system.

The fibrosis also causes stiffness of the vocal tract, the nearby pharynx and skin and reduces vibratory action of the neopharynx. Additional side effects of radiotherapy like xerostomia and thickened secretions also affect voice production^{15,16}. This is important as some patients might have a worse voice outcome due to the added anatomical changes from radiotherapy.

1.7 Voice Rehabilitation

For many patients, voice loss is the most debilitating consequence of total laryngectomy thus voice rehabilitation is an integral part of comprehensive patient care when managing carcinoma of the larynx. There are several methods employed in re-establishing communication. Conservative methods include whispering, miming sign language and oesophageal speech. In whispering, the patient uses the air in the oral and pharyngeal space together with appropriate speech movements to produce a weak and aphonic sound to be heard in a very quiet place.

Oesophageal speech first described by Strübing and Landois in 1889 involves using the oesophagus as an air reservoir and releasing it during speech thereby vibrating the

pharyngo-oesophageal segment to produce speech¹⁷. The simplicity and low complication rate are why this method was the standard of care in the mid-1980s post total laryngectomy and currently is in low resource setups. However, the small oesophageal air reservoir of 50 mls only allows a few syllables at a time and not all patients can master this technique.

It's been observed that only a third of laryngectomees are able to use oesophageal speech satisfactorily and only 10% are able to speak clearly^{18,19}. The most common limitations of oesophageal voice include low pitch, reduced loudness and ability to only speak in short phrases as it depends on a small oesophageal air reservoir.

Patients unable to master oesophageal voice can have the option of an electromechanical device. This is based on the principle that vibration of the oral and upper airway muscles produces a sound. The electromechanical device helps to enhance upper aerodigestive system vibration and also amplify the sound thus produced. The main disadvantages of this are production of an electrical monotonous robot-like voice with an accompanying electrical buzz which makes hearing in ambient noise environment difficult and the use of only one hand each time during speech.

Depending on resource availability, surgical approach to the voice rehabilitation where a communication is created to divert air from the trachea to the oesophagus, through a tracheoesophageal fistula and later placement of a tracheoesophageal prosthesis (TEP) is employed. The device has a one-way valve which allows air to divert from the trachea to the oesophagus, creating a large reservoir, mimicking physiological levels. With the help of inbuilt vibratory reeds, the patient is able to produce sound. The device can be placed primarily during the same surgery as the total laryngectomy or later after healing has occurred.

It affords the patient, immediate phonation, longer phonation time, louder volume and better intelligibility. It is however fraught with problems like aspiration, wound infection, stoma dehiscence, oesophageal perforation, dislodgement and dependence on health providers for the change of prosthesis. Despite it being expensive, even in resource limited countries, tracheoesophageal speech has been shown to be as effective in voice rehabilitation and to have comparable outcome to developed countries²⁰

1.6 Voice Assessment

Laryngeal voice outcome assessment has rapidly evolved over the past 20 years. For the alaryngeal voice, most studies consider 3 types of assessment 1) perceptual voice scale, 2) self-rating questionnaires and 3) acoustic and instrumental measurement²¹. Perceptual analysis

involves judgement of a voice sample by an expert or untrained listener, judging voice characteristics and deviation from normal.

Acoustic tests make use of a computerised program to analyse a voice recording. Self-rating questionnaires makes use of reports from the patients about their voice and quality of life. Observers and clinicians often underestimate severity of symptoms and make assumptions about patients' experiences where clinicians' and observers' assessment frequently deviate from patients' perception ^{15,21}. The patient is often a reliable source pertaining to their own experience.

The Voice Handicap Index (VHI) is a self-assessment questionnaire that is currently regarded as the gold standard for voice pathology assessment. It has been translated and validated in several languages and countries. In the development of the VHI, laryngectomees contributed a significant portion, 26% n=17/65 candidates used for the preliminary VHI formulation ^{22,23}.

The VHI (Appendix III) consists of 30 questions on voice related aspects of a patient's life. The patient is asked to read a statement and responds with how frequently the statement applies to his or her life on a scale of 0 to 4 (0: Never, 1: Hardly ever, 2: Sometimes 3: Almost always 4: Always).

The paper has 3 subscales; physical, functional and emotional with 10 questions in each section. It explores the effect of the voice change on daily activity; the functional section explores the patient's perception of his/her voice characteristics while the emotional section delves into the patient's response to the problem. Each segment has a potential score of 0-40 from no handicap to maximum handicap. On combining the sections, the total VHI has a potential score range of 0-120 graded as mild 0-30, moderate 31-60 and severe 61 to 120 ²².

2.0 CHAPTER TWO: LITERATURE REVIEW

According to the World Health Organisation (WHO), a handicap is a disadvantage to an individual that results from an impairment or disability and as a result limits the fulfilment of a normal functional role depending on age, sex, social and cultural factors^{24,25,26}. Several studies have been done to show the voice related limitations of laryngectomy and the negative impact on voice related quality of life. In a study to assess the quality of life amongst laryngectomees in a laryngectomy support group in Kenya, voice was a top three concern to affect quality of life out of the twelve domains candidates were questioned on. This reiterates the importance and impact of voice on quality of life²⁷.

Using two voice questionnaires, including the VHI to assess the patient perception of voice following total laryngectomy, Rohan et al showed that 38% of patients had mild, 37% had moderate and 25% had severe voice handicap following total laryngectomy. This negatively impacted their QOL especially in the functional and physical domains with mean scores of 15.8 and 13.6 respectively²⁸. These findings were echoed by Lundstrom et al who also used the VHI on 43 patients post laryngectomy and noted that the most affected domains were also the functional and physical domains²⁹. The mean VHI score was 48 which falls in the moderate range.

Speech rehabilitation has universally been shown to improve QOL as it empowers and enables patients to reclaim a vocal identity. Singer et al measured speech intelligibility at six months and one year after total laryngectomy and showed improvement of speech in both objective and subjective measures. Patients who received rehabilitation had better objective speech intelligibility and showed more improvement than those who did not³⁰. Triple et al conducted a retrospective study to find out if rehabilitation had any effect on VHI and quality of life. A statistically significant correlation was found between rehabilitation and all speech groups even though TEP users needed an adjustment period before significant improvement was noted³¹. There is controversy over the best mode of rehabilitation. Some of the studies support different speech rehabilitation options post total laryngectomy while others show no difference between the various modes of alaryngeal speech. Evans et al carried out a study to compare the VHI of patients using Tracheoesophageal prosthesis and those using non-surgical means of communication.

The study included electrolaryngeal speech, oesophageal speech, writing and mouthing in the non-surgical arm. No significant difference was found between the surgical and non-surgical groups and therefore the outcomes were deemed comparable ³². Another study by Maikabel et al compared the more common non-surgical rehabilitation methods based on pairwise comparisons of QOL outcomes, tracheoesophageal speech had similar VRQL compared to oesophageal speech and both performed significantly better than electrolaryngeal speech whose score improved with longer time of use post total laryngectomy and in older age.

In addition, acoustic analytical comparison of oesophageal speech and tracheoesophageal speech to normal voice, showed that tracheoesophageal speech is fairly similar to the normal speech due to more regular vibratory patterns and an efficient respiratory reserve (lungs) which gave a better voice quality and longer phonation time.

Vocal rehabilitation should depend on resource availability, affordability, centre expertise, patient preference and anticipated post-operative vocal utility.

Stuart et al conducted audit of patients post total laryngectomy in West Scotland. The study compared the voice outcomes in patients post total laryngectomy only to those who had also received radiotherapy either after total laryngectomy as post-operative radiotherapy or before salvage total laryngectomy surgery in order to determine the effects of radiotherapy on functional outcome. Radiotherapy was shown to have a significant negative effect on voice and swallowing outcome and that tracheoesophageal prosthesis/TES had better outcomes compared to other communication methods following radiotherapy.

Rahan also showed that the VHI functional aspects were negatively affected by age and radiotherapy. However, Karlson et al debated that majority of patients with carcinoma of the larynx have an impaired voice quality prior to radiotherapy and only voice rehabilitation could give a significant difference in voice related quality of life ³³.

This study aims to ascertain the proportions of the different rehabilitation modalities utilized by laryngectomees on follow up at KNH, with the aim of assessing the QOL associated with each rehabilitation option and how factors like radiotherapy, age and time since surgery may affect their VHI. It also aims to compare our results with the other aforementioned studies.

3.0 CHAPTER THREE: STUDY JUSTIFICATION & METHODOLOGY

3.1 Study Justification

Total laryngectomy (TL) is one of the mainstay treatment methods for cancer of the larynx. The removal of the voice box impedes the natural voice production by affecting both the quality and volume of the sound produced thereafter. This has been shown to have a negative effect on the biopsychosocial state of the patient. There is a dearth of studies done in Kenya and in Africa, showing the impact of TL and speech rehabilitation on the voice from the patients' perspective and their QOL after TL. By assessing the post-operative level of handicap, the study will assist head and neck surgeons and voice therapists in giving comprehensive care to laryngectomees.

3.2 Research Methodology

3.2.1 Study Question

What is the voice handicap in patients after total laryngectomy?

3.2.2 Study Objectives

3.2.2.1 Broad Objective

To determine the level of voice handicap in patients who have undergone total laryngectomy at the Kenyatta National Hospital

3.2.2.2 Specific Objectives

- a) To assess the biopsychosocial impact of voice changes in patients after total laryngectomy
- b) To assess the distributions of different voice rehabilitation methods available at the KNH
- c) To assess the impact of different voice rehabilitation methods on voice handicap

3.2.3 Study Type

This was a descriptive cross-sectional study.

3.2.4 Study Area

The study was conducted at the KNH- ENT outpatient clinic over a period of 6 weeks from April 2021 to May 2021.

3.2.5 Study Population

The participants were 44 adult post laryngectomy patients who were either on follow up at the KNH-ENT outpatient clinic or coming for the monthly post laryngectomy support group meetings.

3.2.6 Inclusion Criteria

Patients who had undergone total laryngectomy for carcinoma of the larynx and were willing to give consent.

3.2.7 Exclusion Criteria

- a) Patients unable to or unwilling to give consent
- b) Patients with complications that might affect voice at the time of study.
- c) Patients who had total laryngectomy less three months prior to enrolment into the study.

3.3 Sample Size Determination

At the Kenyatta National Hospital there are 60 patients registered in the post laryngectomy group. Using 60 as the study population size to calculate for a finite population, the Krejcie Morgan formula was employed as follows ³⁴:

Formula:

$$n = \frac{Nz^2pq}{E^2(N - 1) + (z^2pq)}$$

Where:

n =desired sample size

N = population size: 60

Z= value from standard normal distribution corresponding to desired confidence level (1,96 for 95% confidence interval)

p= expected proportion of total laryngectomy

q=1-p

E =desired precision (0.05)

Therefore:

$$n = \frac{60 \times 1.96^2 \times 0.5 \times 0.5}{0.05^2(60 - 1) + (1.96^2 \times 0.5 \times 0.5)}$$

$$n = 52.0119$$

The sample size was 44 **participants** which was 85% of the desired sample size

3.4 Sampling Technique

Convenience sampling technique was employed until the sample size was reached.

3.5 Tools

The following tools were employed:

- a) Demographic and clinical history data sheet
- b) The VHI questionnaire

3.6 Study Procedure

In this study, participants on follow up after total laryngectomy at KNH- ENT clinic and in the post laryngectomy support group were the target population. The ones who met the inclusion criteria had the study explained to them by the principal researcher. Those who agreed to participate in the study gave written informed consent (Appendix III).

The participants then filled a data sheet where demographic data and relevant past medical history was collected. The participants then filled the Voice Handicap index form (Appendix III). Any sections that the participants needed explanation were elucidated by the principal researcher. Patients who had difficulty with reading or comprehending the questionnaires were assisted by the principal investigator in the language that they were most comfortable with between KiSwahili and English. The data forms were checked for completeness before submission and entry into the final combined data sheet.

3.7 Sampling Procedure Flow Chart

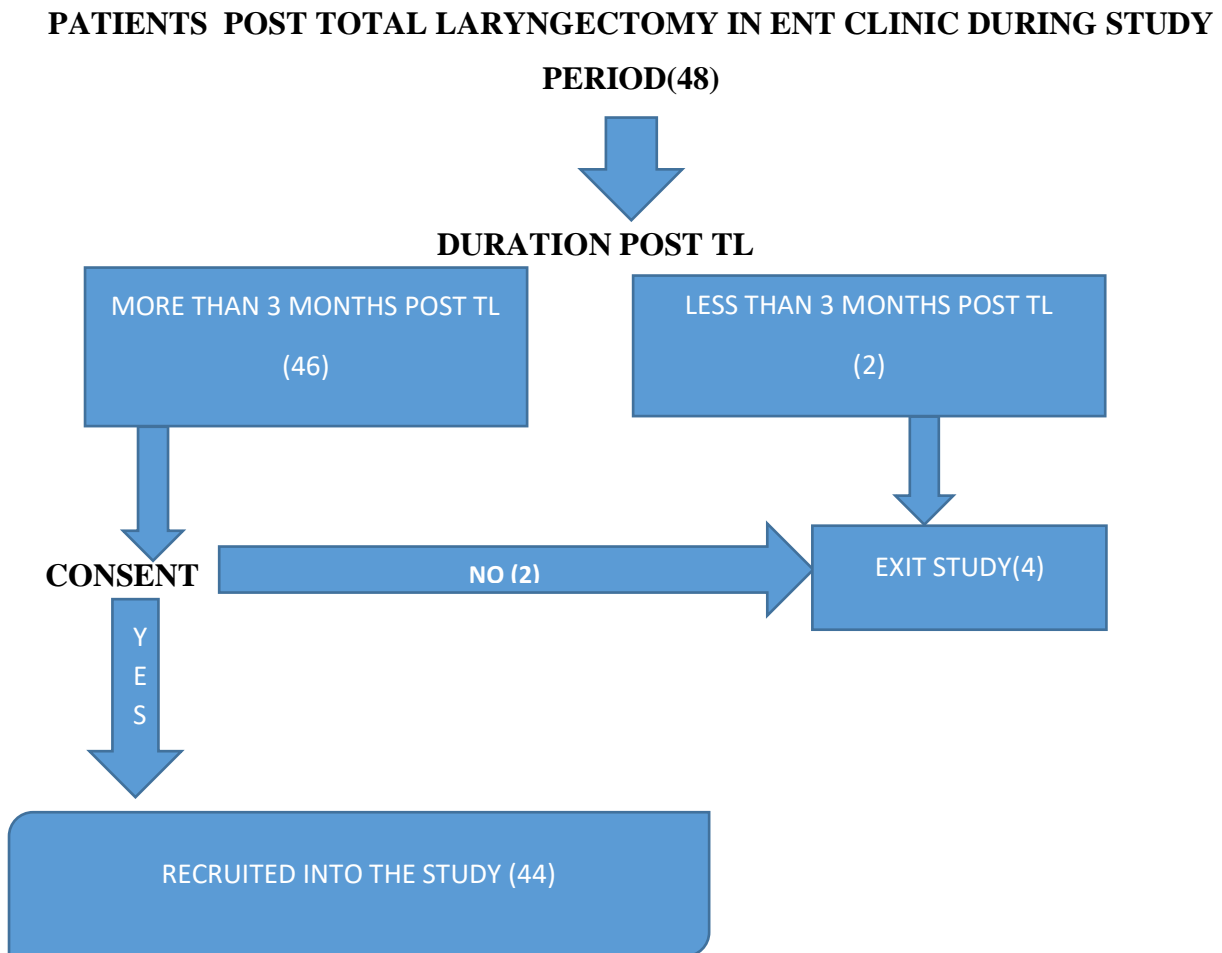


Figure 2: Sampling procedure flow chart

3.8 Data Management

The data was collected using a data collection sheet and entered in an excel spread sheet. At the end of data collection, the excel spread sheet was exported into a computer database using statistical package for social sciences SPSS version 22.

3.9 Data Analysis

Data analysis was conducted using SPSS statistics version 22. The participants were grouped mainly into age groups of ten and method of voice rehabilitation. The data was presented in frequencies, percentages, means and standard deviations for continuous variables. Categorical variables were analysed by calculating percentages. The relationships between participants' characteristics and the VHI were determined by conducting T test and chi-square tests. A P value of < 0.05 was used as the standard for statistical significance. A bivariate regression model was used to determine relationships between dependent and independent variables.

3.10 Quality Control

Quality control was a continuous process throughout the study to maximise validity and reliability of the study findings.

- a) The principal investigator facilitated all the data collection interviews for the clinico-demographic questionnaire and the VHI questionnaire
- b) The data collection tool was cross checked for completeness and errors in entry and corrected.
- c) The qualitative and quantitative data was crosschecked for inconsistencies which were be rectified.

3.11 Ethical Considerations

The research was carried out after approval from the KNH/UON ethics and research committee (ERC). A detailed explanation of the study was given to each participant to giving a written informed consent. Participants who opted out, continued to receive services with no discrimination. Participants did not incur additional costs by taking part in the study. Patients were anonymised by use of assigned study numbers in order to maintain confidentiality. All data collection sheets and any copies of the data were kept safely by the principal investigator and were not be shared with unauthorised personnel.

Once the study was complete, all raw data collection was coded and backed up for further study. The results of the study shall be presented to the UON and the Kenyatta National hospital as a thesis. The findings shall also be disseminated in academic meetings, scientific conferences and in journals or newspapers where necessary. There were no conflicts of interest in this study by the principal investigator, supervisors and the hospital.

4.0 CHAPTER FOUR: RESULTS

4.1.0 Socio-demographic characteristics

This section shows the socio-demographic characteristics of the study participants. The variables being age and sex.

4.1.1 Distribution of participants by gender

The study population was predominantly male at 95.5% with a male to female ratio of 21:1 as shown in figure 3 below.

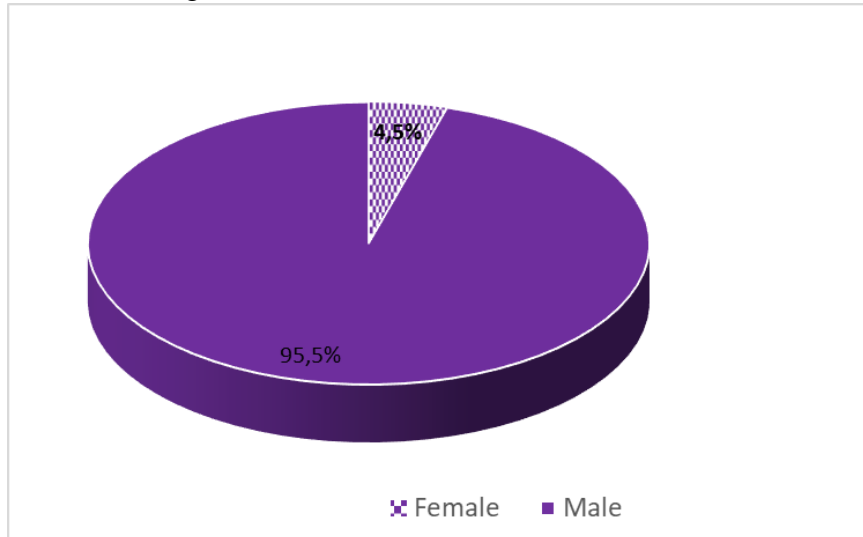


Figure 3: Gender distribution of the participants post total laryngectomy

4.1.2 Distribution of participants by age

The age range for the participants spanned from 36 to 73 years with a mean age of 59.6 years. The 51-60 age range had the highest proportion of study participants as illustrated in figure 4

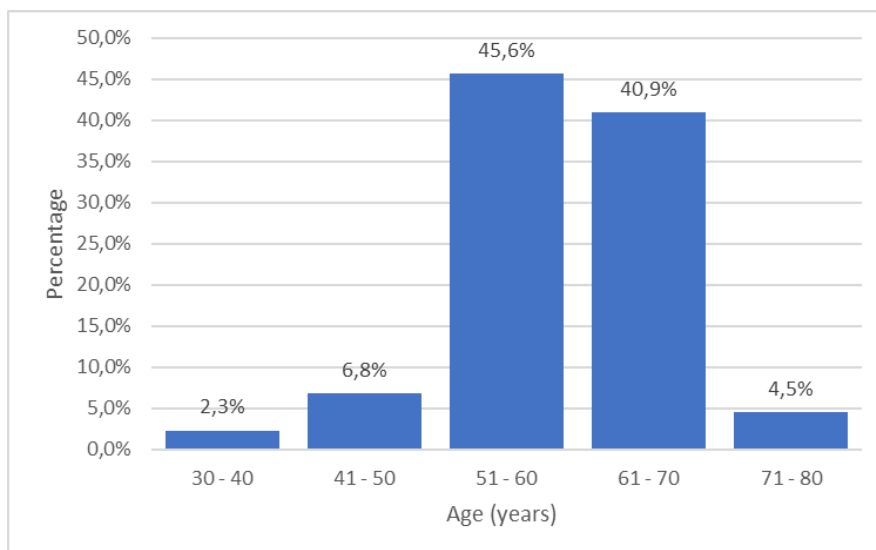


Figure 4: Age distribution of participants

4.2 Time since total laryngectomy

The mean time post total laryngectomy was 61.36 months with a standard deviation of 61.8. The minimum was 3 months and the maximum was 324 months as shown in Figure 5 .

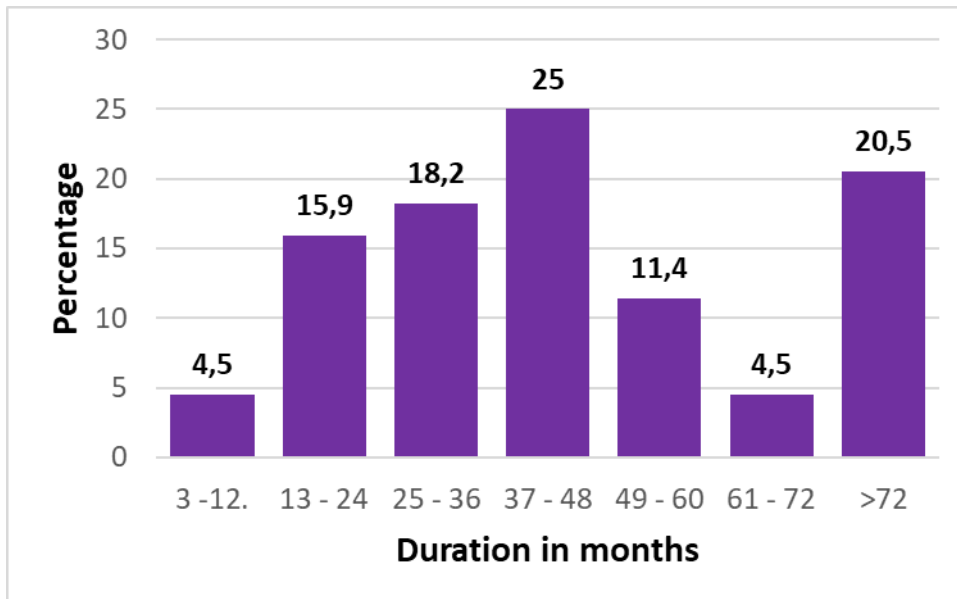


Figure 5 Time in months since total laryngectomy

4.3 Radiotherapy

Most of the participants (93.1%) received radiotherapy, 4/41(10%) had salvage surgery after radiotherapy as shown in figure 6.

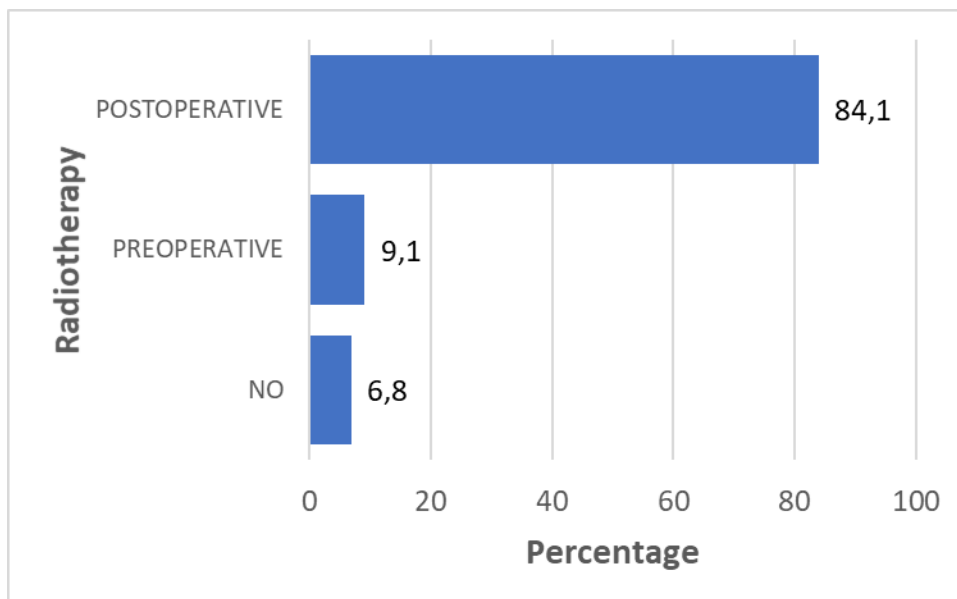


Figure 6: Timing of radiotherapy

4.4 Pre-operative voice counselling

In preparation of the impending voice loss, all the participants received counselling from medical personnel and the support group in various combinations preoperatively. Most (91%), received counselling from a surgical doctor and 9 % received from a speech therapist and/or the support group. This is broken down in table 2 below.

Table 1: preoperative voice counsellor distribution

Source of counselling	Frequency	Percentage
Doctor only	33	75%
Doctor + Speech therapist	5	11.36%
Doctor + Support group	2	4.55%
Support group only	2	4.55%
Speech therapist only	1	2.27%
Speech Therapist + support group	1	2.27%
Total	44	100%

4.5 Voice rehabilitation awareness

The least known voice method was oesophageal speech, it reported a 34,1% improvement in awareness after surgery. All patients knew about electrolarynx before and after surgery as shown in figure 7.

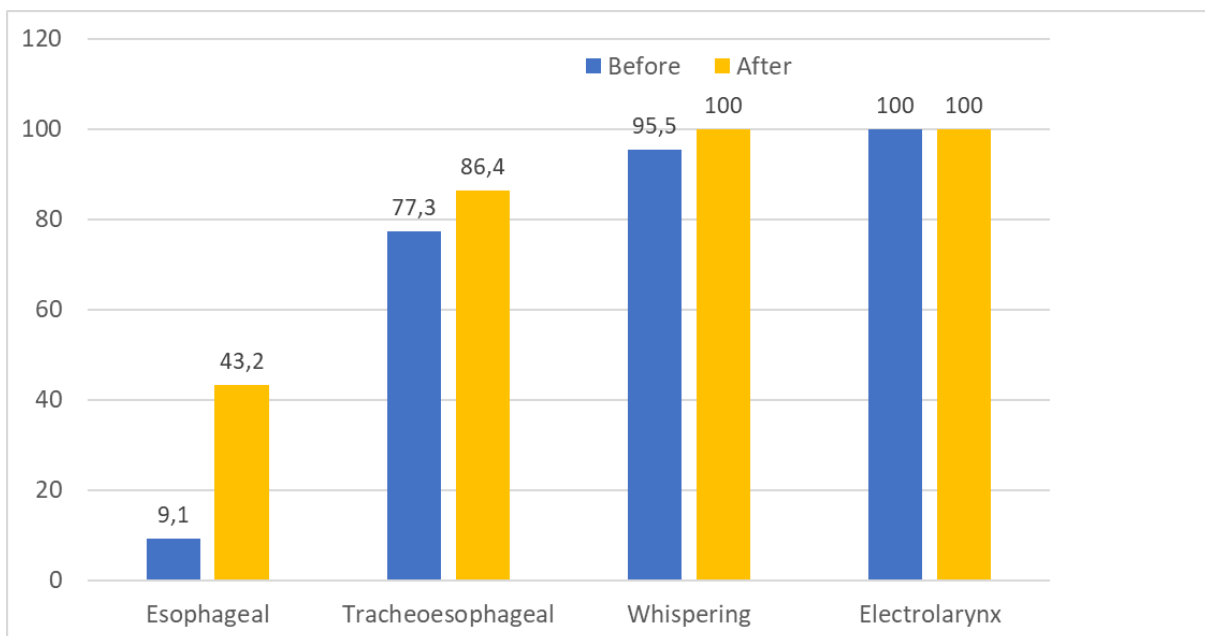


Figure 7: Voice rehabilitation methods patients were aware of before and after surgery

4.6 Current voice method

Most of the participants, 32 (72.7%) were using whispering as a method of communication at the time of the study while 10 (22.7%) were using the electrolarynx, 2 (4.5 %) used the tracheoesophageal prosthesis and no one was using oesophageal voice. This is shown in the pie chart below

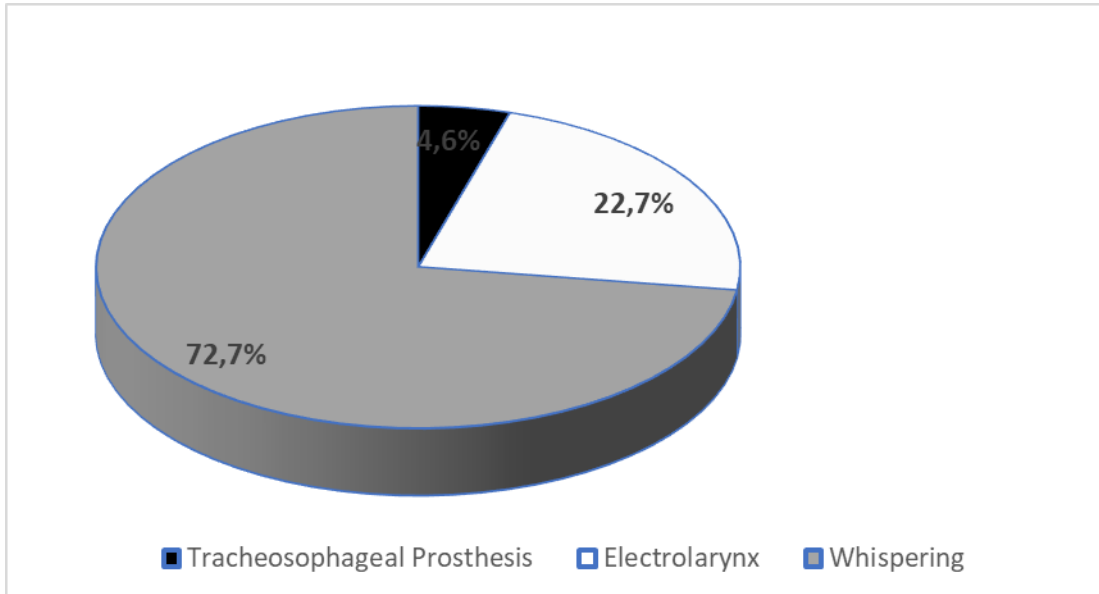


Figure 8: Rehabilitation methods patients were using at the time of the study

4.7 Reality compared to expectations

As an overall assessment of the level of their handicap, participants were asked how the voice reality compared to their expectations prior to surgery and most respondents found reality to be better than their expectation as shown in the pie chart below.

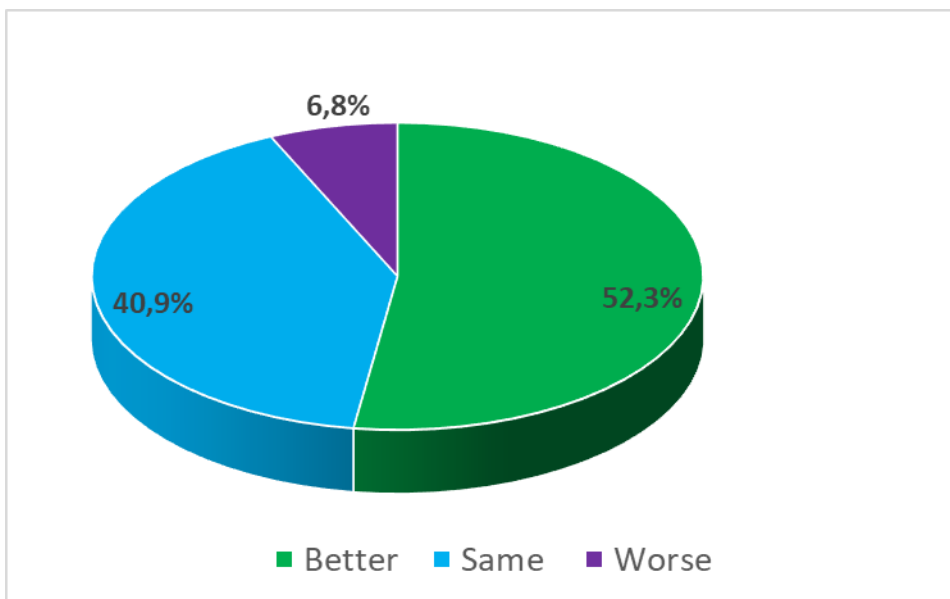


Figure 9: Voice reality compared to preop expectations

4.8 VHI score

The mean VHI score for the group was 17.95. Most patients (88,64%) had a mild handicap;4,55% had a moderate score and only 6.8% had a severe score. The physical domain scored higher than the emotional and functional domains, all were within the mild voice handicap range for individual domains.

Table 3 VHI score summary

VHI Range	Frequency	Percentage
Mild (0-30)	39	88.6%
Moderate (31-60)	2	4.6%
Severe (61-120)	3	6.8%

4.9 Individual rehabilitation method VHI means

Participants who were using whispering as a vocal rehabilitation had a mean total score of 19.6, for tracheoesophageal prosthesis the mean was 13 and the mean for electrolarynx was 13.6. The total means and domain individual group for each rehabilitation method are shown in the figure below. All the total score and domain score means fell in the mild range for total VHI score and individual domains.

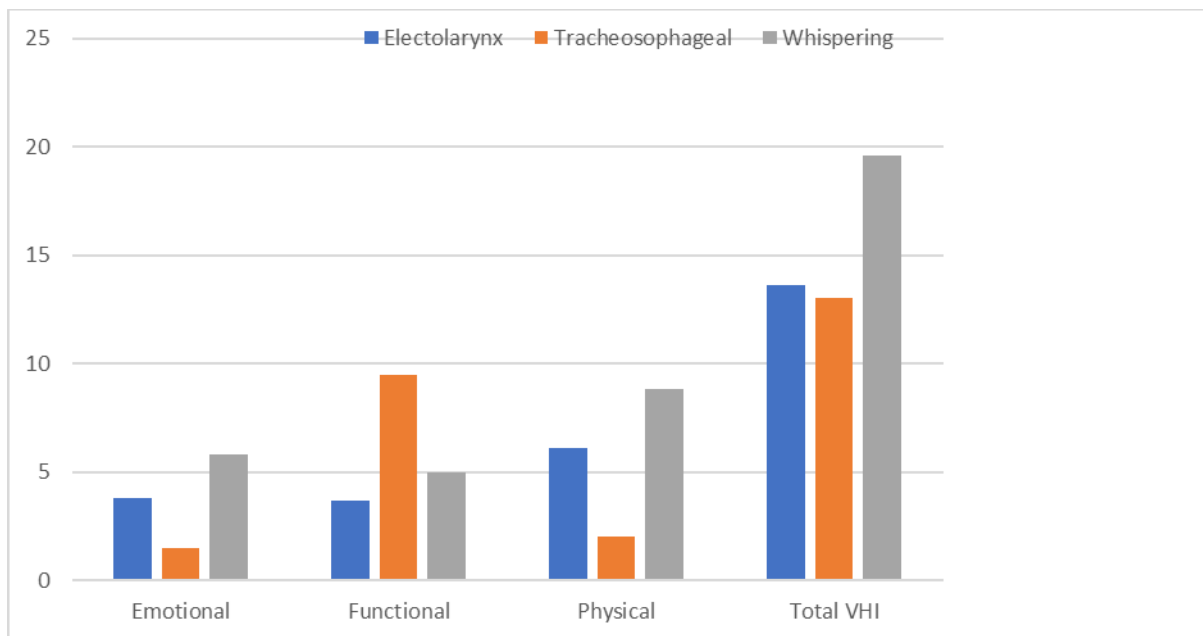


Figure 10. VHI scores for individual rehabilitation methods

4.10 Table 4: correlation of demographic and clinical features and VHI

Variable		Counts	Individual domains						Total VHI	Mean VHI	P value	
			Emotional	P value	Functional	P value	Physical	P value				
Gender	Female	2 (4.5%)	13	0.039	3.5	0.62	8.5	0.45	50	25	0.29	
	Male	42 (95.5%)	4.81		4.95		7.86		740			17.62
Age	<40	1 (2.3%)	4	0.674	7	0.156	17	0.283	28	28	0.462	
	41-50	3 (6.8%)	5.3		6.33		1.67		40			13.33
	51-60	20 (45.5%)	4.65		4.25		8.6		350			17.5
	61-70	18 (40.9%)	5.06		4		7.1		291			16.17
	>71	2 (4.6%)	12		16		12.5		81			40.5
Reality v Expectation	Better	23(52.3%)	3.4	0.001	4	0.001	6.3	0.001	316	13.7	0.001	
	Same	18(40.9%)	4.2		2.67		6.6		243			13.5
	Worse	3 (6.8%)	24.3		25		27.7		231			77
Time post laryngectomy (months)	3-12	2 (4.6%)	15	0.037	23	0.001	20	0.001	116	58	0.0004	
	13 – 24	7 (15.9%)	10.6		9.4		15.6		250			35.6
	25 – 36	8 (18.2%)	4.3		2.4		6.6		106			13.3
	37-48	11 (25%)	3.8		2.8		7		150			13.6
	49-60	5(11.4%)	2.6		3		8.6		71			14.2
	61-72	2(4.6%)	5.5		3.5		3.5		25			12.5
	>72	9(20.5%)	2.7		3.4		2		73			8.1
Current voice method	Tracheoesophageal	2 (4.6)	1.5	0.4911	9.5	0.5233	2	0.294	26	13	0.624	
	Electro-larynx	10 (22.7)	3.8		3.7		6.1		136			13.6
	Whispering	32 (72.7)	5.8		4.97		8.8		628			19.63
Radiotherapy	No	3 (6.82)	1.3	0.354	4.67	0.749	6.33	0.582	37	12.3	0.824	
	Pre-op	6 (13.6)	7.8		3		5.33		97			16.17
	Post op	35 (79.6)	5.06		5.23		8.46		656			18.74

The sex of our participants had no significant impact on the total VHI score with a p-value 0.29. However female participants had a significantly worse score in the emotional domain (p-value 0.039). There was a linear association between age and total VHI Scores with a p value of 0.0674. As age increased the total VHI score increased. There was no significant change in the individual domain scores as age progressed.

On analysis of how time affected the voice handicap, the total score and the individual domains improved after the first 2 years post surgery and this was statistically significant as shown in Table 4 above

Overall, there was a significant association between type of counsellor and the VHI scores with p value of 0.020. Significant differences for Total VHI scores were found between those counselled by doctor vs doctor/ speech therapist (p value = 0.025), and those counselled by doctor/support vs doctor/speech therapist (p value 0.093). For emotional scores, significant differences were found between doctor and Doctor/speech therapist (p value = 0.053) and significant differences were also found between doctor vs doctor/speech therapist in the functional scores(p value 0.009).

Patients' reality and expectation were compared with the VHI scores. Significantly worse total and domain scores were found in those who reported worse reality compared to better reality ($p = 0.001$) and worse reality compared to same reality (p value 0.001).

We analysed the association between voice handicap and method of rehabilitation used and found the results displayed in the table 4 above. There was no statistically significant difference in the 3 methods of rehabilitation in the total VHI and across the domains.

There was no significant difference in VHI scores between those who received radiotherapy and those who did not and the timing of the radiotherapy also had no impact with a p value of 0,824. There was also no significant difference between the individual domain scores

4.9 DISCUSSION AND RECOMMENDATIONS

Treatment for laryngeal cancer may involve multiple approaches including surgery and radiotherapy in various combinations and both are employed in advanced disease. Voice related QOL has become an important aspect in total patient care of laryngectomees. The purpose of this study was to investigate the various modes of vocal rehabilitation and levels of voice handicap amongst patients who had undergone total laryngectomy at the Kenyatta National Hospital.

Our study had a male preponderance of 95.5% in accordance with the predominantly male laryngeal cancer population at the KNH, Menache et al reported a male predominance of 96% amongst laryngeal cancer patients at the KNH³⁵. Carcinoma of the larynx occurs more frequently in males (94%) than in females. It has been observed that males consume more alcohol and cigarettes than women³⁶. A quality-of-life study on Kenyan laryngectomees in 2016 had 95% males.²⁷

The mean total VHI score for the whole study population was 17.95, this falls in the range of mild voice handicap (<30)²². Most of the participants, 39 (88.6%) had a minimal handicap on VHI scale, 2 (4.6%) had moderate handicap and 3(6.8%) had severe handicap. The individual domain score total means were also within the mild handicap range: functional 6.5, physical 7.2 and emotional 6.5. This reflects a much lower handicap than found commonly in literature. Moerman et al had 44% as moderately disabled and 21 % as mildly disabled while assessing handicap in TES users³⁷. The high rate of participant satisfaction in our study may reflect the success of presurgical counselling which was most often done by the doctors probably with detailed explanation about the consequences and functional results of surgery resulting in 92% of the study population reporting that their vocal reality was better or the same as expected. We can also infer that the ability to adapt and compensate for voice loss is highly individual and to a certain degree independent of the presence of an actual voice. In his study of laryngectomees using tracheoesophageal voice in India, Agarwal et al inferred that those from low socio-economic status have more social support as they live in family units compared to developed country nuclear setups³⁸. In addition to family support, our participants had a laryngectomy support group where participants felt a sense of belonging as they shared experiences and solutions to any issues and this might have had a good impact on satisfaction as well. Aswani et al, reported that 90% of the participants found their voice to be the same or better than the preoperative voice²⁷.

In this study, we found that 72.7% of participants used whispering, 22.7% used electrolarynx, none used oesophageal speech and only 4.5% used tracheoesophageal speech. This is different from the global picture as tracheoesophageal speech is the gold standard voice rehabilitation method due to its ease of use and a voice that closely resembles the normal voice. Mourkabel et al's study, most of his patients (56%) used tracheoesophageal speech and none used whispering³⁹. Tracheoesophageal prosthesis has a high initial cost of acquiring it and inherent recurring costs as it requires frequent changes of the prosthesis and the costs of managing possible surgical complications. Oesophageal speech has a steep learning curve in trying to convert a belch into audible speech and normally only 10% of laryngectomees get an audible voice^{18,19}. There are a few speech therapists per population as reported in 2018, Kenya only had 28 speech therapists for a population of 48 million and Kenyatta Hospital has 3⁴⁰. None of our patients had received any formal training on oesophageal speech and very few participants were aware of this method before and after laryngectomy. The plausible explanations for why we had more voiceless rehabilitation includes the high cost of alternative methods and inadequate numbers of speech therapists to help with rehabilitation and hence lack of alternative speech methods.

Participants in the whispering group had the highest mean total VHI score of 19.6 physical score of 8.8, emotional score of 5.8 and a functional score of 4.9. Participants in the tracheoesophageal voice group had a total mean of 13, physical score of 2, emotional score of 1.5 and a functional score of 9.5. Electrolarynx users had a mean total of 13.6, emotional score of 3.8 and functional score of 3.7 and physical score of 6.1. The total scores and individual domain scores for each method was within the mild range. The low VHI across all modes of rehabilitation also reflects that laryngectomees did not view their current situation as a handicap and had found ways to adapt sufficiently according to their day-to-day voice needs.

No association was found between total VHI and domain scores and method of rehabilitation. The greatest difficulty in the functional domain was surprisingly encountered in individuals using tracheoesophageal voice, this was an average for 2 candidates and might have created bias. In this domain, patients were mainly bothered by communication in a noisy room and calling out throughout the house. Electrolarynx users and whisperers had the most voice related problems in the physical domain followed by emotional domain. In the physical domain, respondents most frequently encountered problems with the voice giving out in the middle of speech and people asking "what's wrong with your voice." Emotional domain had the best (lowest) score across all methods, however a few candidates felt annoyed when people asked

them to repeat. Rohan also found no significant difference between total and subdomain VHI scores of surgical and non-surgical rehabilitation of laryngectomees ²⁸.

The age of our participants ranged from 36-73 years (mean 59) and the 51- 60 age range had the highest number of participants. This is also comparative with an epidemiology study by Duffy et al that states that laryngeal cancer occurs through the 4th to 7th decade and most cases occur in the 6th decade ⁴¹. Age had a significant correlation with the total VHI score (p value 0.001), which was worse in older patients. Generally, voice capacity reduces with increasing age. Hodge et al demonstrated that voice intensity is reduced in elderly patients ⁴².

In this study, gender had no significant effect on the total VHI score. Females had a significantly higher score in emotional domain (p value 0.039). Lee et al used a different QOL questionnaire and found females to have a worse emotional outcome post laryngectomy ⁴³. We can infer that even if both sexes were affected by the same health problem (laryngectomy), they reacted to it differently on an emotional level and this might have been compounded by issues beyond voice.

Despite an expected voice worsening from radiotherapy due to fibrosis, mucositis and oedema, we did not find any correlation between, radiotherapy and vocal rehabilitation awareness and total VHI scores neither did the timing of the radiotherapy make a difference.

Conclusion: Most patients at KNH had no voice rehabilitation and used whispering as the mode of speech and have low VHI scores, similar to mild vocal handicap. Tracheoesophageal prosthesis and electrolarynx had better voice handicap outcomes even though it was not statistically significant. This study has shown that non-surgical voice rehabilitation may be useful in cases where surgical voice rehabilitation is not available.

Limitations

Only two laryngectomy support group sessions were done due to the intercounty COVID travel restrictions that's why we didn't achieve the study population.

Lack of a validated and translated VHI questionnaire in Swahili language, this could have contributed to ambiguity in the questions.

The long form VHI scale is structured, comprehensive and organized but time consuming. It also provides a degree of redundant information and has no room for explanations to qualify responses.

Recommendations

All total laryngectomy patients are to get counselling from a doctor and a speech therapist before surgery. More speech therapists are required to train patients and increase the proportion of rehabilitated patients post laryngectomy. We also recommend a follow up study to validate and translate the VHI to Swahili version and /or another study looking at broader view of quality of life in this group this might entail using a redacted VHI 10 and another questionnaire to assess quality of life outside of just the voice.

TIMELINE

PERIOD	ACTIVITY
January 2019-June 2020	Proposal writing
September 2020	Proposal Presentation
October-April 2021	Ethics approval
April- May 2021	Data Collection
May 2021	Data Analysis
May 2021	Presentation of Results

BUDGET

ITEM	UNIT PRICE	COST (KSH)
Flash disk	2 000	2 000
Statistician	30 000	30 000
Printing	10 per page	5 000
Binding	500	5 000
Photocopying services	3	10 000
Publishing fee	45 000	45 000
Ethics approval	2500	2500
Research assistant	15 000	15 000
TOTAL		112 500

This study was self-sponsored, funded by the principal researcher.

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APPENDICES

Appendix I: Participant Information and Consent Form (English)

Title of Study: Assessment of voice disability in patients post total laryngectomy at the
Kenyatta National Hospital

Principal Investigator\and institutional affiliation: Dr. Sibanda Michelle Winfred

Introduction:

I would like to tell you about a study being conducted by the above listed researcher. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

What Is This Study About?

The researcher listed above is interviewing individuals who had total laryngectomy for carcinoma of the larynx. The purpose of the interview is to find out how they are managing with their voice after the operation voice. Participants in this research study will be asked questions about their voice and how it has affected their lives. There will be approximately thirty-three participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

What Will Happen If You Decide To Be In This Research Study?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately ten minutes. The interview will cover topics such as how you feel about your current voice.

After the interview has finished, you will be allowed to go about your other activities of the day.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include to get more information concerning the study.

Are There Any Risks, Harms Discomforts Associated With This Study?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. Also, event recalls may be stressful. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

Are There Any Benefits Being In This Study?

You may benefit by receiving free health information and counseling. We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand patient's view of our treatment. This information is a contribution to science and all patients who may have laryngectomy in the future.

Will Being In This Study Cost You Anything?

There shall be no cost incurred by participating in the study

What If You Have Questions In Future?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

What Are Your Other Choices?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

Consent Form (Statement of Consent)

Participant’s statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to have (define specimen) preserved for later study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name:

Participant signature / Thumb stamp _____ **Date** _____

Researcher’s statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____ **Date:** _____

Signature

Role in the study: _____ *[i.e. study staff who explained informed consent form.]*

For more information contact _____ at _____ from _____ to _____

Witness Printed Name *(If witness is necessary, A witness is a person mutually acceptable to both the researcher and participant)*

Name _____

Contact information _____

Signature /Thumb stamp: _____

Date;_____

For more information about your rights as a research participant you may contact any of the following:

Principal Researcher:

Dr. Michelle W Sibanda,
Resident in ENT-Head & Neck Surgery,
University of Nairobi
Tel. No : 0707 600 204
Email tianafiso@gmail.com

Supervisors;

Dr. Peter Mugwe,
Consultant ENT Head & Neck Surgery,
University of Nairobi
Tel. No: 0722513778
Email: drmugwep@gmail.com

Dr. Sophie Gitonga,
Consultant ENT Head & Neck Surgery
Tel. No:0722867302
Email: drsophiegitonga@gmail.com

Or

The Secretary,
KNH/UoN Ethics and Research committee,
Kenyatta National Hospital Nairobi,
Tel 2726300 Ext 44355.
Email. uonknh-erc@uonbi.ac.ke
Website: <http://www.erc.uonbi.ac.ke>

Appendix II: Participant Information and Consent Form (Kiswahili)

Fomu ya Makubaliano

Mada ya Utafiti: _____

Mtafiti Mkuu: _____

Watafiti Wasaidizi: _____

Utangulizi:

Ningependa kukueleza kuhusu utafiti unaofanywa na watafiti walioorodheshwa hapo juu. Fomu hii itakuwezesha kufanya uamuzi wa kuhusishwa katika utafiti huu. Unakubalika kuuliza maswali kuhusu umuhimu wa utafiti huu, kitakacho fanyika ukujihusisha katika utafiti huu, faida au madhara ya utafiti huu, na mambo mengine yoyote kuhusiana na utafiti huu. Tutakapo jibu maswali yako yote kikamilifu, unaweza kukubali au kukataa kuhusishwa katika utafiti huu. Mpanilio huu unaitwa “idhini wa habai”. Baada ya kuelewa na kukubali kuhusishwa katika utafiti huu, nitakuomba utie sahihi katika fomu hii. Unapaswa kuelewa yafuatayo: i) Uamuzi wako ni wa huru ii) Unaweza kujiondoa katika utafiti huu wakati wowote bila maelezo iii) Kukataa kuhusishwa katika utafiti huu hautaathiri matibabu yako katika hospitali hii au nyingine. Tutakupea nakala yako ya fomu hii.

Je ninaweza kuendelea? Ndio/ La

Utafiti huu umeithinishwa na tume ya maadili na utafiti wa Hospitali Kuu ya Kenyatta nambari _____

Utafiti Huu Ni Juu Ya?

Watafiti hawa watafanya mahojiano kwa wagonjwa waliofanyiwa upasuaji wa koo. Kusudi wa mahojiano ni kujua namna upasuaji wa koo kunaadhiri sauti ya wagonjwa. Wahusiwa wataulizwa maswali kuhusu kuadhirika kwa sauti yao kwa kutumia fomu. Kutakuwa na wahusiwa thelathini na tatu katika utafiti huu watakao chaguliwa kwa nasibu. Tunaomba ruhusa kwako kuhusishwa katika utafiti huu.

Nini Kitafanyika Nikihusishwa Katika Utafiti Huu?

Ukikubali kuhusishwa katika utafiti huu, yafuatayo yatafanyika:

Utaweza kufanyiwa mahojiano kwa njia ya siri ili uweze kujibu maswali bila wasiwasi. Mahojiana yatachukua muda wa dakika yasiyozidi kumi. Mtafiti atazungumzia mada ya kuadhiriwa kwa sauti ya wagonjwa wa upasuaji wa koo. Baada ya mahojiano utaruhusiwa kuendelea na mipango yako ya siku.

Tutaomba uweze kutupatia nambari yako ya simu tuweze kuwasiliana nawe zaidi. Nambari yako itatumika na wahusika wa utafiti huu pekee bila kupewa mtu mwingine yeyote. Kuwasiliana na wewe itakuwa kupata ujumbe zaidi kuhusu utafiti huu.

Je, Ku Madhara Yanayotokana Na Utafiti Huu?

Utafiti wa kisayansi, unaweza kukuadhihi kijinsia, kisaikolojia, kijamii, kiwiliwili na kihisia. Kuhusishwa katika utafiti unaweza kuadhihi faragha kwa nafsi yako. Maelezo yote utakayotupatia yatawekwa kwa njia ya siri. Utaweza kutambulika kwa nambari ya siri katika rekodi ya kompyuta itakayotumika na makatasi yote kuwekwa katika kabati itakayofungwa. Kuna uwezekano kuwa bila idhini yetu mtu kupata rekodi yako. Maswali mengine katika utafiti huu yanaweza kukuletea usumbufu na unaruhusiwa kukataa kuyajibu. Watafiti wote ni wataalamu katiak utafiti. Iwapo utahisi usumbufu wowote katika utafiti huu, wasiliana na watafiti wasaidizi au mkuu mara moja kwa nambari katika nakala hii. Utaweza kutibiwa kwa madhara madogo au kutumwa kwa mhudumu anayefaa.

Je, Kuna Faida Ya Utafiti Huu?

Utweza kufaidika kwa kujua kwa kiasi gani upasuaji ya koo utakuwa umekuadhihi sauti. Utaweza pia kupata matibabu iwapo utahitaji matibabu zaidi. Majibu utakayo tuambia yatawezesha kujua zaidi kuhusu kuadhihika kwa sauti za waliofanyiwa upasuaji wa koo. Utafiti huu pia utachangia katika mikutano ya kisayansi.

Je, Kuhusishwa Utanigarimu Pesa Ngapi?

Hakuna malipo yoyote utahitajika kufanya katika utafiti huu.

Je, Utapata Kurudishiwa Pesa Utakayotumia Katika Utafiti Huu?

Hakuna gharama ya ziada itakayo kupata katika utafiti huu.

Iwapo Una Maswali Baadaye?

Unaweza kuwasiliana na watafiti kwa nambari za rununu zilizowekwa katika nakala hii. Unaweza kupiga simu au kutuma ujumbe mfupi kwa mtafiti yeyote. Kwa ujumbe zaidi kuhusu haki zako katika utafiti, wasiliana na Katibu mkuu wa tume ya maadili na utafi, Hospitali kuu ya Kenyatta na Chuo Kikuu cha Nairobi kwa nambari ya simu 2726300 Ext. 44102 barua pepe: uonknh_erc@uonbi.ac.ke.

Watafiti watagharamia malipo ya kupiga simu kuhusiana na utafiti huu.

Je Uko Na Uchaguzi?

Kuhusishwa katika utafiti huu ni kwa hiari yako. Unaruhusiwa kukataa kuhusishwa au kujiondoa katika utafiti huu kwa wakati wowote bila dhuluma.

Fomu Ya Makubaliano**Tamko la mshiriki**

Mimi nimesoma au nimesomewa yaliyochapishwa katika fomu hii. Nimeweza kupata maelezo kutoka kwa mtaalamu wa utafiti. Maswali yangu yamejibiwa kwa lugha ninayoelewa. Ninaelewa ya kwamba, kushiriki kwa utafiti huu ni kwa hiari yangu na kwamba ninaweza kujiondoa kwa utafiti huu kwa wakati wowote. Nimekubali kwa hiari yangu kuhusishwa katika utafiti huu Kwa kutia sahihi, sitakuwa nimekata tamaa ya haki zangu kama mhusishwa katika utafiti huu.

Nimekubali kuhusishwa katika utafiti huu: Ndio/ La

Nimekubali kupeana njia za mawasiliano zangu kwa mazungumzo zaidi: Ndio/La

Jina la mhusiwa: _____

Sahihi la mhusiwa / kidole gumba _____ **Tarehe** _____

Tamko la Mtafiti

Mimi, niliyetia sahihi, nimeeleza kwa kina yanayohusiana na utafiti huu na ninatumai mhusiwa ameelewa vyema na kukubali kwa hiari yake kuhusishwa.

Mtafiti mkuu: Michelle Sibanda

Tarehe: _____ **Sahihi** _____

Uhusiano katika utafiti: _____

Kwa mawasiliano zaidi, wasiliana na _____ kwa nambari
_____ saa _____ hadi

Jina la mshuhudia

Jina _____ **Simu ya Rununu** _____

Sahihi/Kidole gumba: _____ **Tarehe;** _____

Appendix III: Data Collection Form

Study Number.....

Date.....

Biodata:

Age.....

Sex.....

Medical history:

- 1) Stage at time of Total Laryngectomy.....
- 2) Time post Total Laryngectomy(months).....
- 3) Post op complications.....
- 4) Radiotherapy: Yes/No
pre/post op
number of cycles
- 5) Vocal rehab method:
 - a) Oesophageal speech
 - b) Electrolarynx
 - c) Tracheo-esophageal prosthesis
 - i. time between surgery and insertion
 - ii. previous communication method
 - d) No rehabilitationstate alternative mode
- 6) Were you informed of potential voice loss pre op?
Yes NO
If yes by whom:
 - a) Doctor
 - b) Speech therapist
 - c) Support group
- 7) What communication options were you given pre op?
 - a) Esophageal Speech
 - b) Electrolarynx
 - c) Tracheo- Esophageal Prosthesis
 - d) None

8) What communication options are you aware of post op?

- a) Esophageal Speech**
- b) Electrolarynx**
- c) Tracheo-Esophageal Speech**
- d) None**

9) How does the reality compare with your expectations?

- a) Worse**
- b) Same**
- c) Better**

Appendix IV: Voice Handicap Index Questionnaire (VHI)

Study Number.....

Date

The following are statements that many people have used to describe their voices and the effects of their voices on their lives. Tick the response that shows how frequently you have the same experiences

Questions

Response

Part One	0-Never	1-Almost never	2 Sometimes	3-Almost always	4-Always
1. My voice makes it difficult for people to hear me					
2. People have difficulty in understanding me in a noisy room					
3. My family has difficulty hearing me when I call throughout the house					
4. I use the phone less often than I would like to					
5. I tend to avoid groups of people because of my voice					
6. I speak with friends, neighbours or relatives less because of my voice					
7. People ask me to repeat myself when speaking face to face					
8. Voice difficulties restrict my personal and social life					
9. I feel left out of conversations because of my voice					
10. My voice problem causes me to lose income					

Part Two	0-Never	1-Almost Never	2-Sometimes	3Almost Always	4- Always
1. I run out of air when I talk					
2. The sound of my voice varies throughout the day					
3. People ask "What is wrong with your voice?"					
4. My voice sounds creaky and dry					
5. I feel as though I have to strain to produce a voice					
6. The clarity of my voice is unpredictable					
7. I try to change my voice to sound different					
8. I use a great deal of effort to speak					
9. My voice is worse in the evening					
10. My voice gives out on me in the middle of speech					
Part Two	0-Never	1-Almost Never	2-Sometimes	3Almost Always	4- Always
1. I run out of air when I talk					
2. The sound of my voice varies throughout the day					
3. People ask "What is wrong with your voice?"					
4. My voice sounds creaky and dry					
5. I feel as though I have to strain to produce a voice					
6. The clarity of my voice is unpredictable					
7. I try to change my voice to sound different					
8. I use a great deal of effort to speak					
9. My voice is worse in the evening					
10. My voice gives out on me in the middle of speech					

Part Three	0-Never	1-Almost never	2-Sometimes	3-almost always	4-Always
1. I am tense when talking to others because of my voice					
2. People seem irritated by my voice					
3. I find other people don't understand my voice					
4. My voice problem upsets me					
5. I am less outgoing because of my voice					
6. My voice makes me feel handicapped					
7. I feel annoyed when people ask me to repeat					
8. I feel embarrassed when people ask me to repeat					
9. My voice makes me feel incompetent					
10. I am ashamed of my voice problem					

Study Number.....

Date

Ifuatayo ni taarifa ambazo watu wengi wametumia kuelezea sauti zao na athari za sauti zao kwenye maisha yao

Questions

Response

Ya Kwanza	0-Kamwe	1- Nadra	2-Mara nyingine	3-Karibu kila wakati	4-Kila mara
1. Watu wanapata ugumu kunisikia kwa sababu ya sauti yangu					
2. Ni vigumu watu kunielewa kunapokuwa na kelele					
3. Nikiwa nyumbani familia yangu hupata vigumu kulisikia ninapoitana					
4. Mimi hutumia simu mara chache kuliko ninavyotarajia					
5. Sipendi kutangamana na vikundi vya watu kwa sababu ya sauti yangu					
6. Mimi huzungumza na majirani au jamaa mara chache kwa sababu ya sauti yangu					
7. Watu huniulizia nijirudie ninapooonea nao uso kwa uso					
8. Shida za sauti zinaadhiri maisha yangu ya kibinafsi na kijamii					
9. Nahisi kupuuzwa nikiwa katika mazungumzo kwasababu ya sauti yangu					
10. Shida yangu ya sauti husababisha nipoteze mapato					

Ya Pili	0-Kamwe	1-Nadra	2-Mara nyingine	3-Karibu kila wakati	4-Kila mara
1. Ninaishiwa na pumzi ninapozungumza					
2. Kiwango cha sauti yangu kinatofautiana siku nzima					
3. Watu huuliza “nini kibaya na sauti yako”					
4. Sauti yangu inaskiika dhaifu nakavu					
5. Ninahisi kana kwamba lazima nijikaze kutoa sauti					
6. Uwazi wa sauti yangu hautabiriki					
7. Ninajaribu kubadilisha sauti yangu kuwa sauti tofauti					
8. Ninatumia bidi kubwa kuongea					
9. Sauti yangu ni mbaya zaidi jioni					
10. Sauti yangu inapotea katikati ya hotuba					

Ya Tatu	0-Kamwe	1-Nadra	2-mara nyingine	3-Karibu kila wakati	4-Kila mara
1. Ninasisitizwa wakati ninazungumza na wengine kwa sababu ya sauti yangu					
2. Watu wanaonekana kukasirishwa na sauti yangu					
3. Napata watu wengine hawaelewi sauti yangu					
4. Shida za sauti yang zinakasirisha					
5. Nimepunguza kuenda sitarehe zangu kwa sababu ya sauti					
6. Sauti yangu inanifanya nihisi kua nina ulemavu					
7. Ninahisi kukasirika wakati watu wananiuliza kurudia					
8. Ninahisi aibu wakati watu wananiuliza kurudia					
9. Sauti yangu inanifanya nihisi sina uwezo					
10. Nina aibu juu ya shida yangu ya sauti					



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Ref: KNH-ERC/A/130

Dr. Michelle Winfred Sibanda
Re. No.H58/88172/2016
Dept. of Surgery (Ear, Nose and Throat)
School of Medicine
College of Health Sciences
University of Nairobi



15th April 2021

Dear Dr. Sibanda

RESEARCH PROPOSAL – ASSESSMENT OF VOICE HANDICAP IN TOTAL LARYNGECTOMY PATIENTS AT THE KENYATTA NATIONAL HOSPITAL (P23/01/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 15th April 2021 – 14th April 2022.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- Submission of an *executive summary* report within 90 days upon completion of the study.

Protect to discover

Kenya National Hospital
P.O. Box 10070 - Nairobi
TEL: 254 20 222000

Dr. Kibung'u

Kenya National Hospital
P.O. Box 10070 - Nairobi
TEL: 254 20 222000

ASSESSMENT OF VOICE HANDICAP IN TOTAL LARYNGECTOMY PATIENTS AT KENYATTA NATIONAL HOSPITAL

by Dr. Michelle Sibanda

Dr. Kibung'u
13/09/2021

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Dr. Kibira G.S.

DEPARTMENT OF SURGERY
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