THE DIAGNOSTIC YIELD OF LARYNGEAL AND PHARYNGEAL PATHOLOGIES DURING UPPER GASTROINTESTINAL ENDOSCOPY AT THE KENYATTA NATIONAL HOSPITAL: A COMPARISON BETWEEN INDIRECT LARYNGOSCOPY AND OESOPHAGOGASTRODUODENOSCOPY FINDINGS

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H58/80930/2015

Masters of Medicine in Otorhinolaryngology, Head and Neck Surgery

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A dissertation submitted in partial fulfillment for the award of Masters of Medicine in Otorhinolaryngology, Head and Neck Surgery

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ABBREVIATIONS

ENT-	Ear nose and throat
GI-	Gastrointestinal
HNSCC-	Head and neck squamous cell carcinoma
IL-	Indirect laryngoscopy
IQR-	Interquartile range
KNH-	Kenyatta national hospital
LPR-	Laryngopharyngeal reflux
Mm-	Millimeters
NBI-	Narrow band imaging
NPV-	Negative predictive value
OGD-	Oesophagogastroduodenoscopy
OSCC-	Oesophageal squamous cell carcinoma
PPV-	Positive predictive value
RFS-	Reflux finding score
SPSS-	Statistical package for social sciences
UGI-	Upper gastrointestinal
UON-KNH ERC-	University of Nairobi –Kenyatta National Hospital Ethics And Research Committee
VL-	Video laryngoscopy
WLI-	White light imaging

ABSTRACT

Background: Evaluation of the larynx and pharynx areas is not always performed during oesophagogastroduodenoscopy(OGD) despite the oropharynx and laryngopharynx being bypassed to get to the oesophagus. Laryngopharyngeal abnormalities have been picked in up to 5.4% OGDs.

Main objective: To determine the diagnostic yield of laryngeal and pharyngeal pathology during OGD at Kenyatta national hospital (KNH)

Study design and setting: This was a prospective cross sectional study on patients undergoing OGD from February to July 2020 at KNH endoscopy unit.

Methodology: One hundred and twenty-one patients aged 18 years and above were recruited into the study. History and physical examination including video laryngoscopy were done followed by endoscopic evaluation of the pharynx and larynx during OGD.

Data management and analysis: Data was expressed as means and standard deviations. Comparison between subsites and between both endoscopic groups was done using chi-squared. Sensitivity and specificity was calculated using indirect video laryngoscopy as the gold standard. Diagnostic accuracy was obtained using receiver operating characteristics curve. A P-value of <0.05 for a 95% confidence interval was considered significant.

Results

Among 121 patient recruited into the study, 17.35 % had laryngeal and pharyngeal abnormalities on OGD whereas 25.61% had abnormalities on video laryngoscopy(VL).The common pathologies on video laryngoscopy were LPR (10.79%), vocal cord paralysis (8.33%) then laryngeal leukoplakia (2.49%) while vocal cord paralysis (5.69%), LPR (4.96%) ,laryngeal and oropharyngeal leukoplakia (2.49%) were common on OGD. VL had higher odds of diagnosing pathologies of the oropharynx, larynx and hypopharynx compared to OGD. The mean time taken to evaluate the larynx and pharynx was 43±20.9 seconds while OGD procedure took 237.3±106.4 seconds. OGD was 63.4% sensitive and 91.3% specific in diagnosing pathologies of the various subsites, with positive and negative predictive values of 78.9% and 83.0% respectively.

Conclusion

The diagnostic yield of laryngeal and pharyngeal pathologies during OGD is significant and it only requires 43 seconds to do examination. Examination of the larynx and pharynx should be made part of OGD examination and reporting.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background

The rapid increase in upper gastrointestinal endoscopic procedures has led to early detection of precancerous and cancerous lesions which has greatly enhanced the quality of life. Laryngeal and pharyngeal examination is considered a field for the otolaryngologist and not many of the gastrointestinal endoscopists take interest in these areas[(1)] .

The larynx is visualized during endoscopy and the oropharynx and hypopharynx are bypassed during upper gastrointestinal (UGI) endoscopic insertion and therefore various laryngeal and pharyngeal diseases can be detected using upper GI endoscopy. Endoscopy can be combined with conventional white light imaging (WLI) which normally displays the lesions as more hyperemic than the background mucosa but the demarcation line is usually not clear. Endoscopic evaluation can be better enhanced by use of narrow band imaging (NBI). It is useful in identifying superficial esophageal squamous cell carcinoma (ESCC) and head and neck squamous cell carcinomas (HNSCC). Lesions appear brownish in colour with better demarcations on NBI compared to WLI which makes taking a biopsy easier [(2)].

1.2 Anatomy of the Pharynx and Larynx

The pharynx is subdivided into three parts: nasopharynx, oropharynx and hypopharynx. Nasopharynx extends from the base of skull to the inferior extent of the soft palate where it transitions to the oropharynx. The hypopharynx extends from the superior border of the epiglottis to the inferior border of the cricoid cartilage where it becomes continuous with the oesophagus. Anteriorly, it has the laryngeal inlet and the posterior parts of the arytenoid and cricoid cartilages. The pyriform recesses are situated on each side of the laryngeal inlet [(3)]. The hypopharynx is closely related to the larynx. It consists of the pyriform sinuses, post-cricoid region and posterior pharyngeal walls [(4)]

The larynx consists of three major subsites: supraglottis, glottis and subglottis . The supraglottis consists of suprahyoid epiglottis, infrahyoid epiglottis, aryepiglottic folds ,arytenoids and false vocal cords. The glottis consists of the true vocal cords, anterior and posterior commissures. (Figure 1).The oropharynx has the tonsils and their corresponding pillars anterolaterally, base of tongue anteriorly and mucosa overlying the constrictor muscles posteriorly (Figure 2).During endoscopy the oral cavity, oropharynx, nasopharynx, hypopharynx and larynx can all be examined.

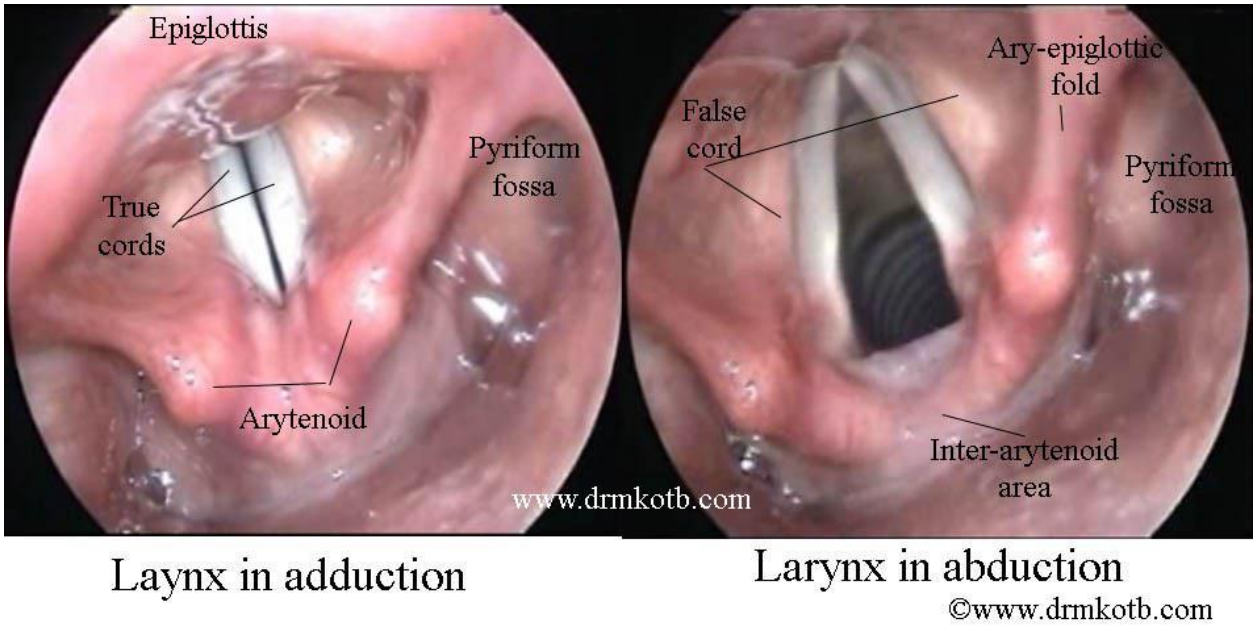

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Figure 1:Normal endoscopic view of the larynx[5]

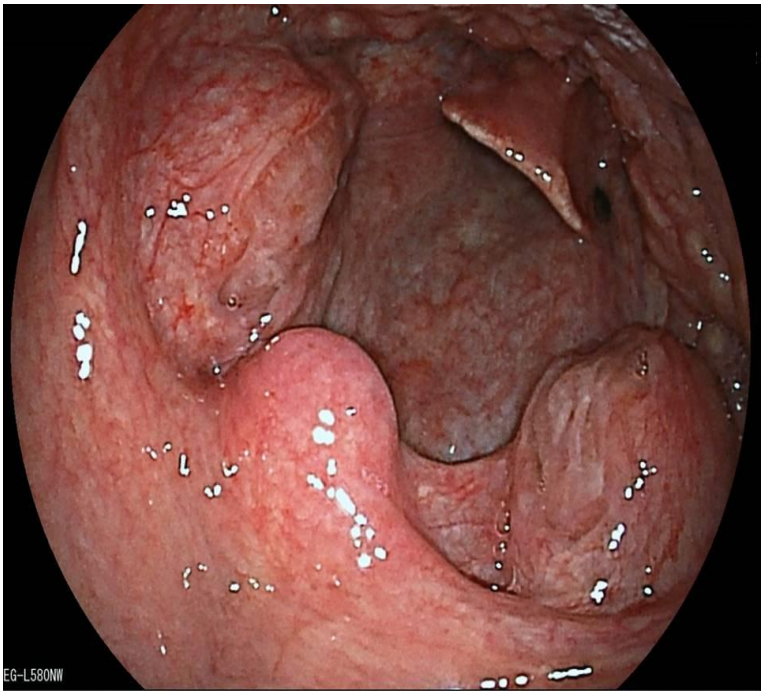

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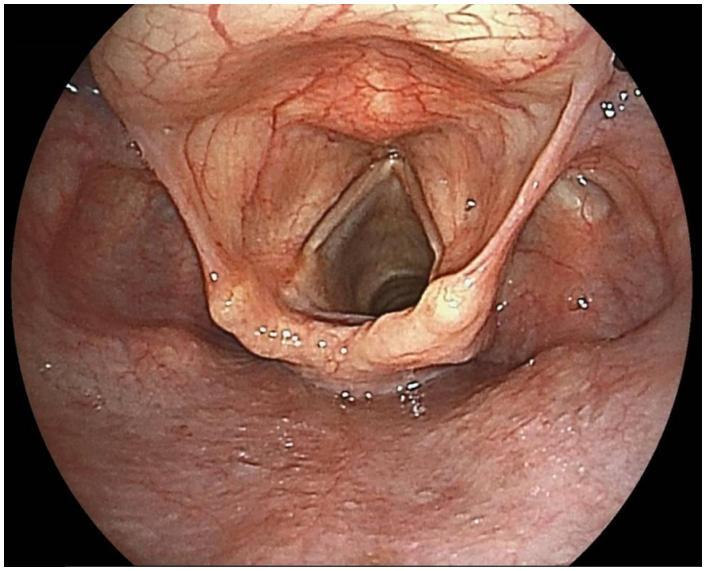
Figure 2: Normal endoscopic view of the oropharynx[5]



Adapted from intechopen.com

Figure 3:Normal endoscopic view of the hypopharynx and larynx[5]

1.3 Presentation of Pathologies of the Larynx and Pharynx

A wide spectrum of laryngeal diseases exist ranging from benign to neoplastic lesions. Benign disesases of the larynx that can be visualized include: vocal cord nodules which occur as a result of voice overuse. They appear as callusses on the vocal cord and prevent the vocal cords from meeting at the midline producing an hourglass deformity on closure resulting in a raspy or hoarse voice. Endoscopically, vocal cord nodules are classically located at the junction of the anterior and middle third of the vocal fold and are mostly bilateral.

Vocal cord polyps are seen mostly unilateral and are seen on the free phonating edge of the cord as pedicled or sessile masses that also prevent adduction of the cords but can also be seen along the superior and inferior borders of the cords. Laryngitis sicca is caused by inadequate hydration of the vocal cords. They appear to have thick sticky mucous or crusting which prevents the fluid movement of the cords in a uniform manner. Presbylaryngis is thinning of the vocal folds muscle tissues with aging.

Endoscopically ,there is loss of volume of the cords with inward curvature (bowing) on movement. Laryngeal spasmodic dystonia may be of adductor ,abductor or mixed type [6]. Laryngitis usually as seen endoscopically has nonspecific features of erythema and oedema of the mucous membranes on the posterior arytenoid and interarytenoid region due to the positional relationship with the upper oesophageal sphincter. Reinke's oedema is swelling within the Reinke's space within which gelatinous substance accumulates. The vocal folds appear enlarged, oedematous with increased vascularity.

Oropharyngeal lesions that may be seen during endoscopy include discoloration of the mucous membranes due to angiodysplasia or Oral candidiasis which is seen as whitish membranous substance on the oral cavity or oropharynx that can be easily scrapped. Tonsillar hypertrophy can be observed and graded.[7]

Precancerous lesions like leukoplakia appear as whitish plaques that cannot be scrapped off easily. It comes about as a result of exposure to irritants or chronic inflammation(8). Erythroplakia which is less common than leukoplakia with a prevalence of less than 1 %, they appear as a fiery red patch with soft velvety homogenous structure that is associated with higher risk of dysplasia or carcinoma. The malignant transformation rate is upto 50%.[9] These lesions can be seen commonly on the buccal mucosa, palate ,tongue and floor of the mouth. Erythroleukoplakia is seen when a lesion has both red and white changes within the same lesion,with either flat or erythematous appearance [9].Masses that are friable with irregular margins and easily bleed on touch are likely to be cancerous and this is confirmed by biopsy tissue taken for histology.

1.4 Challenges Related To Visualization of Laryngeal and Pharyngeal Regions

The section of the oral cavity to the pharynx is the most difficult part to assess during upper gastrointestinal endoscopy. A strong gag reflex despite local anaesthesia with lignocaine spray can make it difficult to examine the larynx and hypopharyngeal areas. A strong or persistent cough reflex can also make it impossible to do a complete examination of the laryngeal and pharygeal areas. Air insufflation can irritate the vocal cords exerting a cough reflex. Early insufflation is therefore not encouraged but instead it should be done when the distal tip of the endoscope enters the upper oesophagus. Forceful manipulation of the endoscope at the piriform sinus region carries a risk of perforation.[10]

Excessive bleeding following biopsy may occur in the laryngeal or pharyngeal areas especially if a mass is likely to be cancerous or is highly vascularized. This presents a challenge especially when bleeding becomes uncontrollable. Adequate local anaesthesia with lignocaine spray and insufflation of air only when the endoscope enters the upper oesophagus will prevent cough reflex. Avoidance of forceful manipulation will prevent perforations. Biopsying of the lesions will be reserved for the theatre setting when a lesion is suspected to be cancerous.

2.0 CHAPTER TWO: LITERATURE REVIEW

There is scarce literature on laryngeal and pharyngeal evaluation during routine oesophagogastroduodenoscopy (OGD) in the African population despite the increase in use of endoscopy for upper gastrointestinal examination. Most of the studies have been done in Asia and Europe with few Publications in east and central Africa.

Upper GI endoscopy has been found to be beneficial during ENT practice. In ENT practice, laryngoscopy is done for most patients. The laryngoscopy can be direct where a rigid or flexible laryngoscope is used or it can be indirect where a laryngeal mirror or rigid or flexible laryngoscope with a camera that can visualize the larynx is used[11]. Patients presenting with hoarseness of voice do not always have laryngeal pathology. Fifty five percent of these patients have been found to have a normal larynx on indirect laryngoscopy but when upper GI endoscopy is done, it reveals presence of gastritis or duodenitis.[12]. Therefore, it is necessary to also do OGD in patients with hoarseness of voice without noticeable laryngeal pathology on laryngoscopy.

A study done in Korea reviewed the lesions that can be observed in the laryngeal and pharyngeal area during the standard upper OGD. A variety of oral, laryngeal and pharyngeal lesions were observed. These included oral candidiasis, leukoplakia, tonsillar hypertrophy, apthous ulcers, Behcet's disease, reflux laryngitis, vocal fold polyps and nodules, vocal cord paralysis, laryngeal and hypopharyngeal masses. A thorough examination of these areas can reveal most of these lesions which could easily be missed if examination of the areas above the oesophagus is ignored. [13]

Cammarota et al looked at 100 patients with reflux and 100 patients without reflux symptoms prospectively. They investigated the accuracy of laryngeal examination during routine UGI endoscopy as a method of screening for laryngeal injury in a series of patients with reflux disease. Sensitivity was 90% for both gastroenterologists and ENT specialists. NPV was 92% for gastroenterologists and 81% for ENT specialists. Laryngoscopy was done to all patients as the gold standard. The kappa coefficient was 0.89 that showed a good agreement of the findings by the ENT specialists and gastroenterologists [14].

This means that endoscopists are preliminarily able to assess the laryngeal and pharyngeal area fairly well and enable referral to otolaryngologist when suspicious lesions are identified.

A controlled prospective study done in Zurich, Switzerland whose aim was to evaluate the positive and negative predictive values of screening the laryngopharyngeal area during routine upper gastrointestinal (UGI) endoscopy looked at 1209 patients over a period of one

year. Sixty two patients were suspected to have laryngopharyngeal abnormalities with twenty six of them confirmed to have pathologies. The commonest finding was chronic laryngitis (26%) followed by Reinke's oedema and others for the benign lesions. Early supraglottic carcinoma T1 N0 was diagnosed and treated with carbon dioxide laser treatment. [15]. Lehman et al did a screening examination of larynx and pharynx areas and found that out of the patients who had abnormalities, 62 % had chronic laryngitis [16]. This was similar to study done in Zurich by Mullhaupt et al. The second abnormality was vocal cord paralysis in twenty percent then leukoplakia in five percent patients. The high percentage of laryngitis patients found in the Lehman study was possibly due to the different methodology that allowed retrograde examination of the larynx and pharyngeal area therefore increasing possibility of oedema. The time range varied from 10 seconds to 4 minutes with a mean time of 30 seconds to evaluate the laryngeal and pharyngeal areas.

A prospective pilot study of 111 patients done in Madison ,USA included all patients undergoing a routine OGD. WLI and NBI of the larynx and hypopharynx prior to carrying out the standard OGD procedure was done. Details on ability to see all anatomical structures, time spent, complications and findings were recorded. Examination of 87% patients was completed. A total of 35.8 seconds was taken to do both WLI (20.2 seconds) and NBI (15.6 seconds). Less than 3% of the patients had minor procedural complications like hypotension, tachycardia and hypoxia. Five percent patients had abnormalities with majority having vocal cord nodules, followed by apthous ulcers and leukoplakia [17].

Saito et al had 224 high risk male patients who were above 50 years of age, smokers and drinkers. They determined the prevalence of pharyngeal carcinoma in asymptomatic high risk patients during UGI endoscopy. Eighty percent of the patients were fully evaluated while 20% had pharyngeal reflux that prevented complete evaluation. Superficial pharyngeal carcinoma was detected in five of the 224 patients i.e. three T1 and two had carcinoma in situ. Mean time taken to evaluate the pharyngeal area was 1.7 minutes and total time mean for the complete endoscopy was 8.9 minutes. NBI detected superficial HNSCC more frequently than WLI did. [18]. When we look at time spent, evaluation of the laryngeal and pharyngeal area can be done by endoscopists during OGD by adding only 30 seconds to 102 seconds to standard OGD time which would go a long way in detecting precancerous or cancerous lesions early.

Failure to complete the procedure without sedation has been associated with larger caliber scopes with outer diameter of more than 9mm, younger age and pre-procedure apprehension[19-20]. The use of topical lidocaine spray for pharyngeal anaesthesia is associated

with less procedural pain, higher procedural completion rate of up to 99% ,better patient and endoscopist satisfaction[21]. Upper GI endoscopy can be performed with or without sedation. The level of accuracy of the results is the same on whether a patient is given sedation or not. The development of small caliber diameter endoscopes of less than 6 mm has permitted performance of unsedated upper GI endoscopy via transoral or transnasal route. Sedation-less endoscopy has been found to be more cost effective, less time consuming and it avoids sedation related complications[22][23]. Feasibility, tolerance and acceptance of unsedated endoscopy versus sedated endoscopy ranges from 80-98% of the patients completing the procedure[24][25].

3.0 CHAPTER THREE: STUDY JUSTIFICATION

The increase of upper gastrointestinal endoscopic procedures has led to early detection of precancerous and cancerous lesions. This has been greatly helpful in improvement of quality of life and cure of cancers that are detected in the early stages. Laryngeal and pharyngeal lesions are generally considered as a field of otolaryngology and therefore most gastroenterologists do not commonly take interest in these lesions during upper gastrointestinal endoscopic examinations. The laryngeal and pharyngeal areas are visualized during endoscopy and the oropharynx and laryngopharynx must be bypassed during upper GIT endoscopic insertion and hence a variety of lesions can be detected if these areas are examined in detail. Studies done have showed that up to 5.4% of all tests done endoscopically in the upper GIT have shown abnormalities in the laryngopharynx(17). This study will demonstrate the laryngeal and pharyngeal lesions that can be observed during a standard upper gastrointestinal endoscopic exam and recommend evaluation of the larynx and pharynx as part of the routine upper GIT endoscopic examination at Kenyatta National Hospital and may give a guide in coming up with a template to facilitate documentation.

3.1 Research Question

What is the diagnostic yield of laryngeal and pharyngeal pathologies during elective upper gastrointestinal endoscopy?

3.2 Main Objective

To determine the diagnostic yield of laryngeal and pharyngeal pathologies during elective upper gastrointestinal endoscopy at Kenyatta National Hospital.

3.3 Specific Objectives

- To determine the observable laryngeal and pharyngeal pathologies during elective upper gastrointestinal endoscopy
- To determine the time taken to evaluate the larynx, oropharynx and hypopharyngeal areas during upper gastrointestinal endoscopy
- To determine the observable laryngeal and pharyngeal pathologies during video laryngoscopy
- To compare the video laryngoscopy and upper gastrointestinal endoscopic findings of the larynx, oropharynx and hypopharynx

3.4 Study Methodology

3.4.1 Study Design

The study design was a prospective cross sectional study

3.4.2 Study Setting

The setting of the study was at the endoscopy unit at Kenyatta national hospital

3.4.3 Study Population

The study population included all patients undergoing elective upper gastrointestinal endoscopic evaluation during the study period in Kenyatta national hospital endoscopy unit

3.4.5 Inclusion Criteria

The inclusion criteria included the following:

a) Adult patients of either sex at least 18 years of age

b) Patients who were undergoing upper gastrointestinal endoscopic evaluation for the first time

c) Patients who gave informed consent to be part of the study

3.4.6 Exclusion Criteria

The exclusion criteria included the following:

a) Patients who were undergoing emergency upper gastrointestinal endoscopic procedure

b) Patients known to have allergy to lidocaine 10% spray that was used in the study

c) Patients with previous neck, laryngeal or pharyngeal surgery

d) Patients in whom examination of the laryngeal or pharyngeal area was not possible due to excessive gag or cough reflex and trismus

e) Patients who were very sick and were not stable enough to undergo the procedure

f) Patients who had impending upper airway obstruction

g) Patients who had previous radiotherapy for any head and neck malignancies

3.5 Sample Size Calculation

According to hospital records at the endoscopy unit in KNH, 844 oesophagogastroduodenoscopies(OGDs) were done over a 1 year period from January 2017 to December 2017.

Sample size will be calculated using the following formula(26)

$$\boldsymbol{n = \frac{NZ^2P(1-P)}{d^2(N-1) + Z^2P(1-P}}$$

Where;

n= sample size with finite population correction

N=population size=844

P=expected proportion= 90% (15)

Z= Z statistic for 95% level of confidence = 1.96

d=margin of error 5%

Substituting in our formula gives a sample size of 118 patients

3.6 Study Tools

a) Olympus endoscopic unit 190 series

b) Conventional endoscope GF-HQ190

c) Data collection sheet (Appendix III)

d) Timer

e) 70 degree Karl storz laryngoscope

f) Camera unit with light source

3.7 Sampling Procedure

3.7.1 Recruitment, Consent and Sampling Technique

Patients undergoing upper gastrointestinal endoscopic exam at the endoscopy unit in KNH were the target population for this study. Once the inclusion criteria were met by the patient, the nature of the study and what was expected was explained to the patient. The patient was then asked to fill the consent form (Appendix I/II). Those who gave written consent were recruited into the study. Consecutive sampling technique was used whereby all patients booked for endoscopy were given a chance to be included in the study. Those who didn't give consent or meet the inclusion criteria were excluded from the study. Figure 4 below shows the procedure for patient selection.

3.7.2 Flow chart showing patient selection

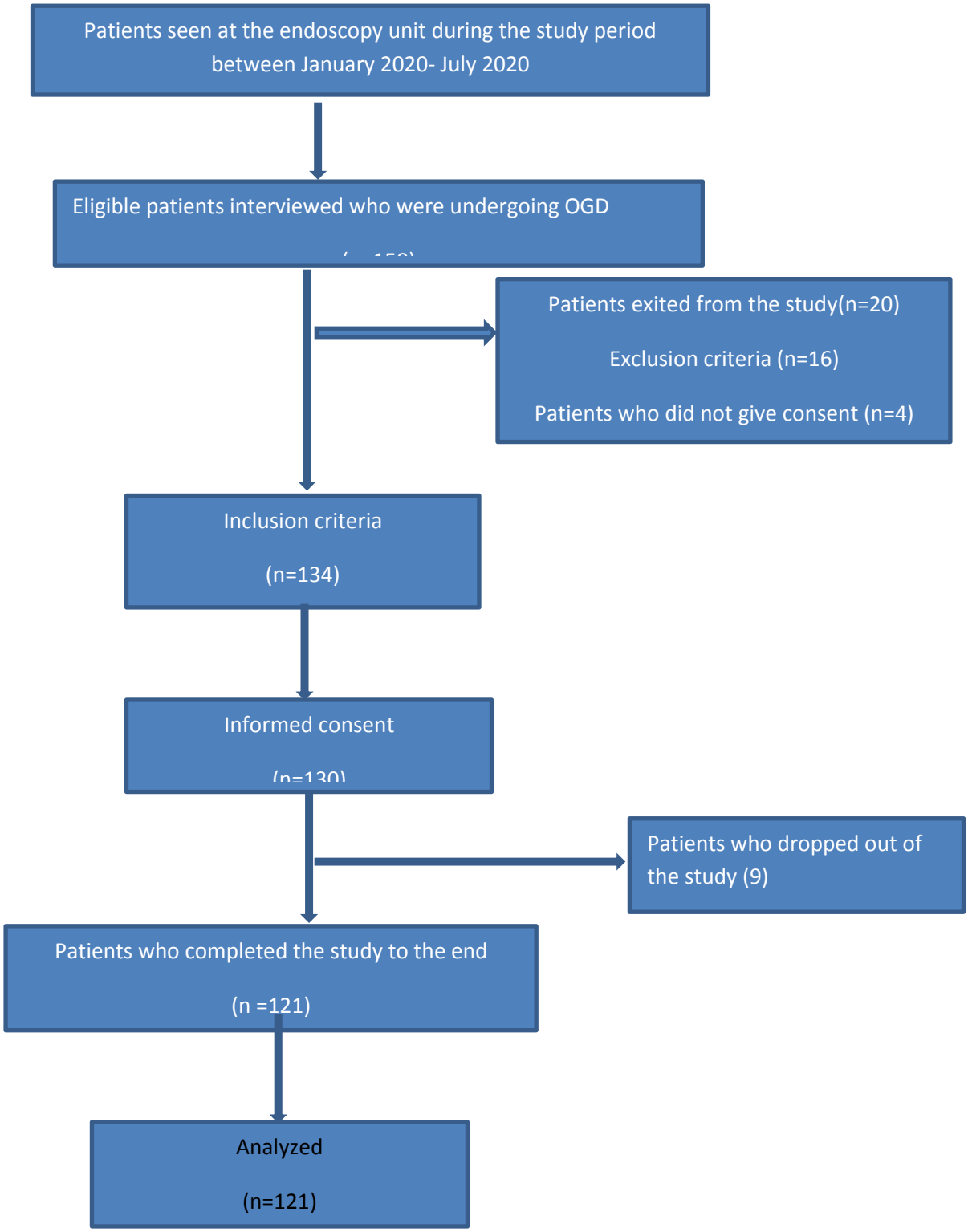


Figure 4: Flow chart on patient selection

3.7.3 Procedure and Data Collection

One hundred and twenty one participants who were recruited into the study underwent history taking and physical examination of the ear, nose and throat including an indirect laryngoscopy done with a laryngoscope in the endoscopy unit. The standard sitting ENT position was used where the principal examiner was seated facing the patient. Xylocaine 10% spray was used as the topical anaesthetic agent and applied to the oropharyngeal area. The patient was then asked to protrude the tongue which was wrapped and held with a piece of gauze with the left hand then the karl storz 70 degree laryngoscope was introduced into the oral cavity with the right hand.

The oropharynx, larynx and hypopharynx were examined and findings recorded on the data collection sheet. The upper GI endoscopic examination was done thereafter by an endoscopist who was blinded to the findings of the principal researcher during indirect laryngoscopy (IL). All the OGDs were done by endoscopists who comprised of general surgery, family medicine and internal medicine consultants doing fellowship in gastroenterology, consultant gastroenterologist and a consultant cardiothoracic surgeon/gastroenterologist. All patients were evaluated with Olympus EVIS EXERA III CV-190 series endoscopy machine. A conventional endoscope GF-HQ190 was used. Xylocaine spray 10% was used as a local anaesthetic prior to insertion of the endoscope and no sedation was given to the patients. The examination of the larynx, pharynx, oesophagus, stomach and duodenum were carried out in the left lateral decubitus position.

The short standard adult Olympus type mouth piece was used. Laryngeal and pharyngeal observation using white light imaging and narrow band imaging was performed in a scheduled manner. Areas with well demarcated brownish irregular microvasculature on NBI were biopsied whenever possible. Examination of the laryngeal and pharyngeal area was performed at the beginning prior to insertion of the endoscope into the oesophagus to prevent any instrumental trauma related hyperemia or oedema of the larynx. The endoscope was advanced under direct vision.

The timer was started when the oropharynx came into view .The observations started from the soft palate, then the uvula and the tonsils bilaterally. The base of tongue, vallecula and epiglottis were then inspected. Further advancement of the endoscope with anterior flexion was done to allow visualization of the arytenoids and aryepiglottic folds. The vocal cords were evaluated at rest and during the phonation of the word “eeee”. The piriform sinus was evaluated with minimal lateral deflection. The post-cricoid region and lateral hypopharyngeal walls were then evaluated. The endoscope was then advanced to enter the upper oesophageal

opening .Time was recorded when the endoscope entered the upper esophageal sphincter. Evaluation of the oesophagus, stomach and duodenum was done. The timer was stopped when evaluation of the 2nd part of duodenum was complete and time taken for the total procedure recorded.

Those patients in whom adequate examination of the laryngeal and pharyngeal area was not possible were excluded from the study. The whole examination of the laryngeal and pharyngeal area was recorded on videotape. Patients with suspected cancerous lesions were sent to the ENT clinic for further evaluation via direct laryngoscopy by the otolaryngologist. All participants continued with the various modalities of treatment as prescribed once the endoscopy was complete and diagnosis regarding the upper gastrointestinal system was made.

3.8 Data Management and Analysis

The collected data was cross-checked, cleaned, categorized and entered using our statistical analysis software package, SPSS version 22. The folder containing our data was password-protected and uploaded to a cloud storage drive and backup was done daily to prevent missing entries. Descriptive statistics such as frequencies and percentages was used to describe demographic characteristics like age and sex and clinical variables like risk factors, clinical findings by both endoscopic modalities and diagnoses.

Measures of central tendency such as mean and standard deviation were used to describe variables with normal distribution while skewed distributions were used in terms of medians and interquartile ranges. Abnormal findings within various subsites were compared in terms of frequency by the chi squared test. Comparison between subsites and between both endoscopic groups were done using fischer's exact test. Sensitivity and specificity was calculated from 4 X 4 tables using indirect video laryngoscopy as the gold standard to get true positives and negatives and false positives and negatives. Diagnostic accuracy was obtained by use of receiver operating characteristics (ROC) curve. A P-value of <0.05 for a 95% confidence interval was the cut off for statistical significance.

3.9 Ethical Considerations

The study started after approval from UON-KNH ERC (P778/09/2019) & the department of ENT surgery. Each patient received counseling & patient education prior to obtaining informed written consent. Patients who gave a signed informed consent were included as participants in the study. Patients who declined to give consent continued to receive treatment as prescribed for their condition. The patients were identified by study numbers and not their

names to enable us maintain confidentiality throughout the process of data collection. All the data collection sheets and soft copy data were kept safely by the principal researcher and were not shared with unauthorized persons.

The results of the study will be submitted to the university in form of a thesis. The Findings of the study will also be shared during presentations in meetings, seminars, conferences, journals and other scientific forums. Hard copies of the study will be availed at the UON department of surgery, college of health science library and the ENT department library. A soft copy will also be available on the University of Nairobi online portal for reference and dissemination. A manuscript will be prepared and submitted for publication in a journal as part of the partial fulfillment of the degree on masters of medicine in ear nose and throat surgery.

4.0 CHAPTER FOUR: RESULTS

The main objective of this study was to determine the diagnostic yield of laryngeal and pharyngeal pathologies during elective upper gastrointestinal endoscopy in Kenyatta national hospital

4.1 Demographic Characteristics of Study Population

A total of 121 participants were recruited into the study. Among these, 62(51%) were males and 59(49%) were females. The mean age of participants was 47.3yrs±16.3yrs and ranged from 18yrs to 88yrs as shown of figure 5 below.

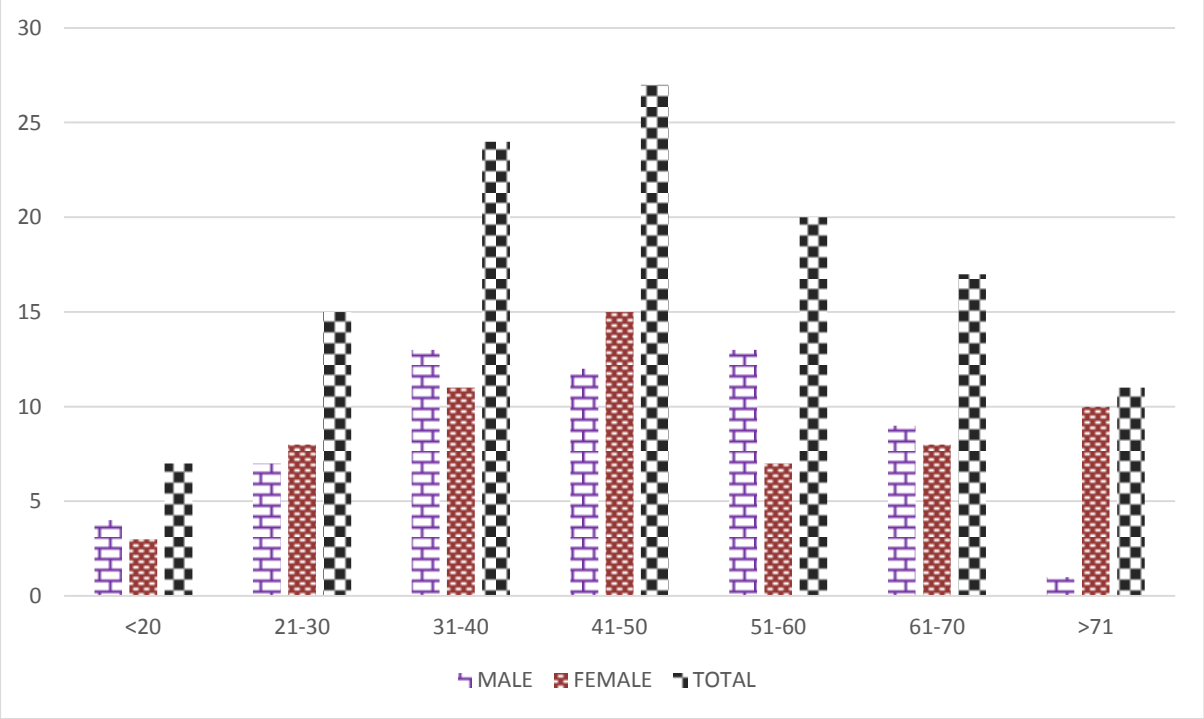


Figure 5: Age-sex distribution of participants

There was a history of smoking in 14(11.6%) of the population with a mean of 15.8±18.9 pack years. Alcohol consumption was reported among 24(19.8%) with a median duration of consumption of 20yrs IQR (12.5yrs to 22yrs). Most of the population 14(56.1%) consumed mixed brews. The main presenting complaints of participants were heartburn 38(31.4%), dysphagia, 36(29.8%), Hoarseness 18(15.1%), odynophagia 13(10.7%), hawking 10(8.3%), globus sensation 8(6.6%) as shown in figure 6 below.

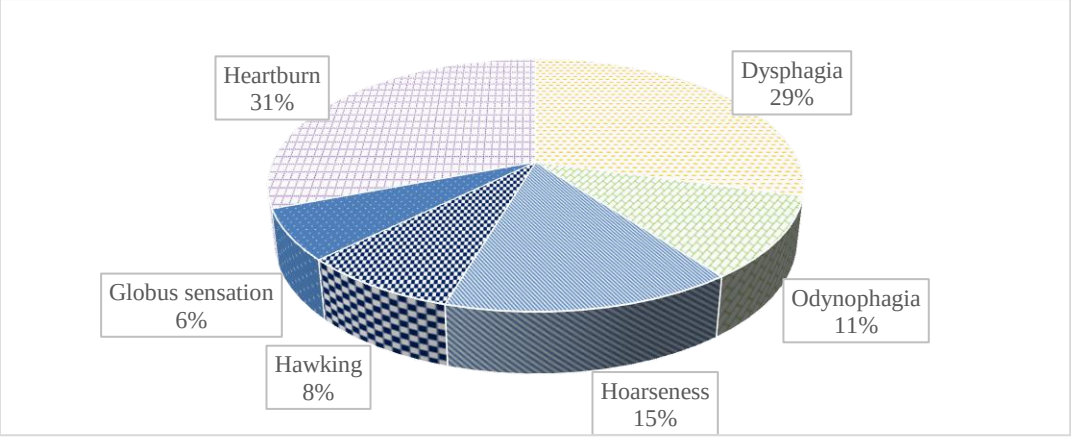


Figure 6: Clinical features distribution.

4.2 Findings on Oesophagogastroduodenoscopy

There were 21(17.35%) abnormalities in the laryngeal and pharyngeal regions on OGD. Majority of the pathologies found during the elective OGD were in the larynx. Vocal cord paralysis was the commonest followed by laryngopharyngeal reflux then vocal cord leukoplakia then one patient with vocal cord polyps. Leukoplakia and candidiasis were noted in the oropharynx. In the hypopharynx region, six patients were found to have features of LPR as shown on table 1 below.

4.3 Findings on Video Laryngoscopy

Table 1: Laryngeal and pharyngeal findings during video laryngoscopy and OGD

Investigative Modality	Subsite	Diagnosis	Frequency	%
Video laryngoscopy	Oropharynx	Tonsil hypertrophy	4	3.33
		Kaposi like lesions	1	0.83
	Larynx	Arytenoid atresia	1	0.83
		edematous arytenoid	2	1.67
		Laryngeal mass	1	0.83
		LPR(Reflux finding score(RFS)>7	13	10.79
		Left FVC edema	1	0.83
		Vocal cord paralysis	10	8.33
		Kaposi like lesions	1	0.83
		Laryngitis sicca	1	0.83
		Laryngeal leukoplakia	3	2.49
		Presbylaryngis	1	0.83
		Vocal cord polyps	1	0.83
	Hypopharynx	Hypopharyngeal mass	1	0.83
		LPR(RFS>7)	10	8.33
OGD	oropharynx	Candidiasis	1	0.83
		Leukoplakia	3	2.49
	Larynx	Vocal cord paralysis	7	5.69
		LPR (RFS>7)	6	4.96
		Vocal cord leukoplakia	3	2.49
		Vocal cord polyps	1	0.83
	Hypopharynx	LPR(RFS>7)	6	4.96

There were 31(25.6%) participants with abnormalities on video laryngoscopy. Most of the pathologies were observed in the larynx. Laryngopharyngeal reflux defined by presence of reflux finding score of more than 7 and vocal cord paralysis formed majority of the findings. There was one patient with a hypopharyngeal mass noted in the right piriform sinus. Biopsy was taken from the piriform sinus mass and was later confirmed to be a well differentiated squamous cell carcinoma. One patient with retroviral disease and not on antiretroviral therapy was found to have Kaposi like lesions in the oral cavity, oropharynx and larynx.

4.4 Time Taken To Evaluate the Laryngeal and Pharyngeal Areas during OGD

Mean time taken from oropharynx to esophageal opening was 43±20.9 seconds and ranged from 7 to 108 seconds, and 237.3±106.4 seconds for the total OGD procedure and ranging from 65 to 650 seconds as shown in figures 7 and 8 below.

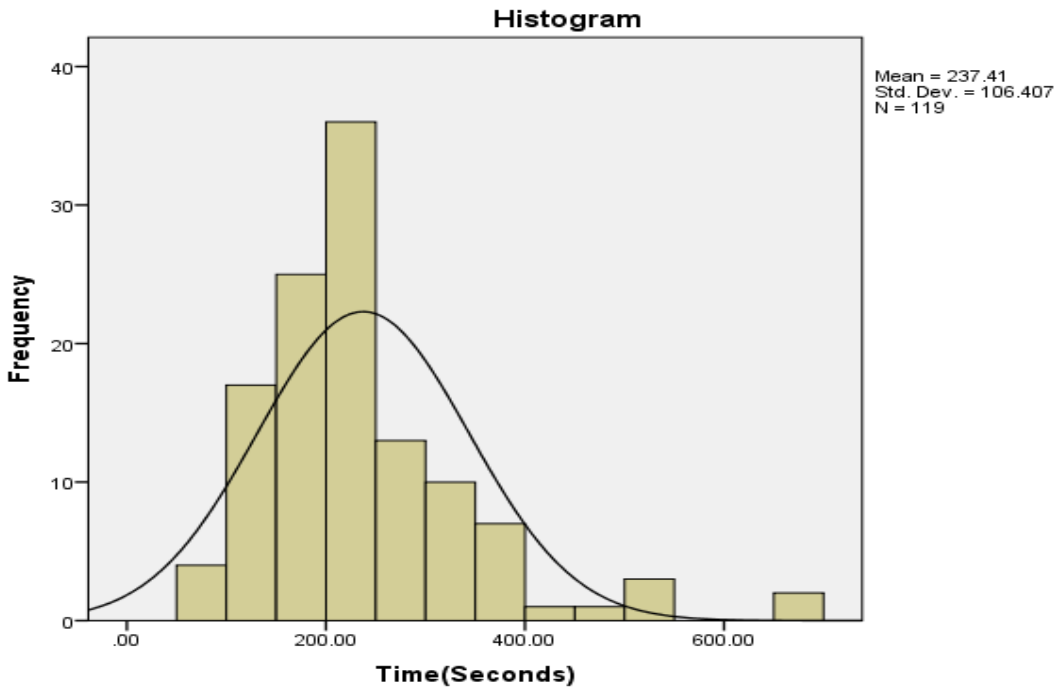


Figure 7: Frequency distribution curve for time taken for OGD

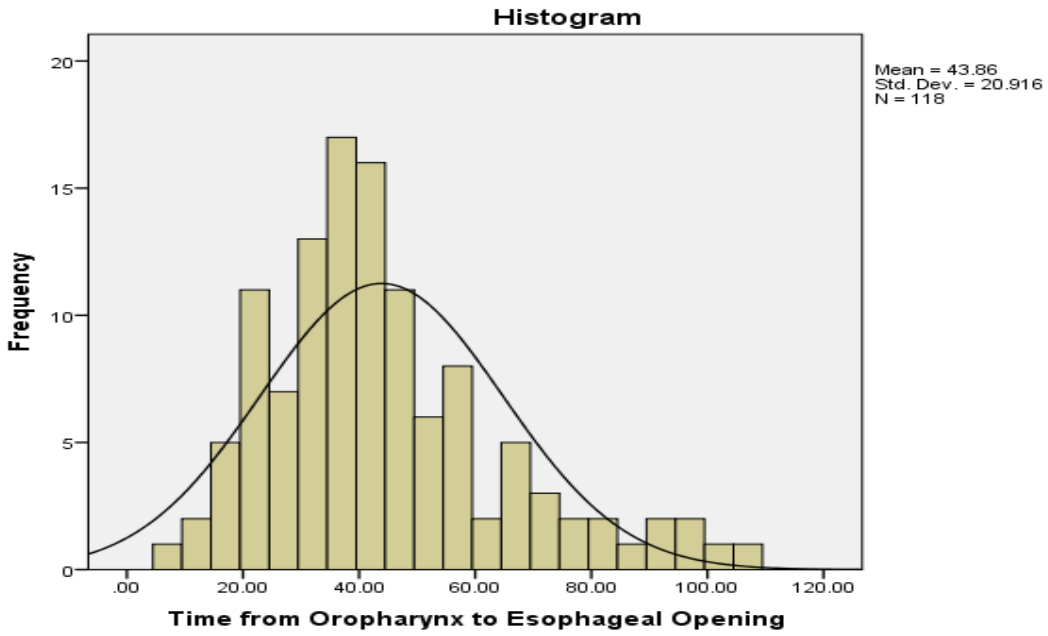


Figure 8: Frequency distribution curve for time taken to evaluate larynx and pharynx during OGD

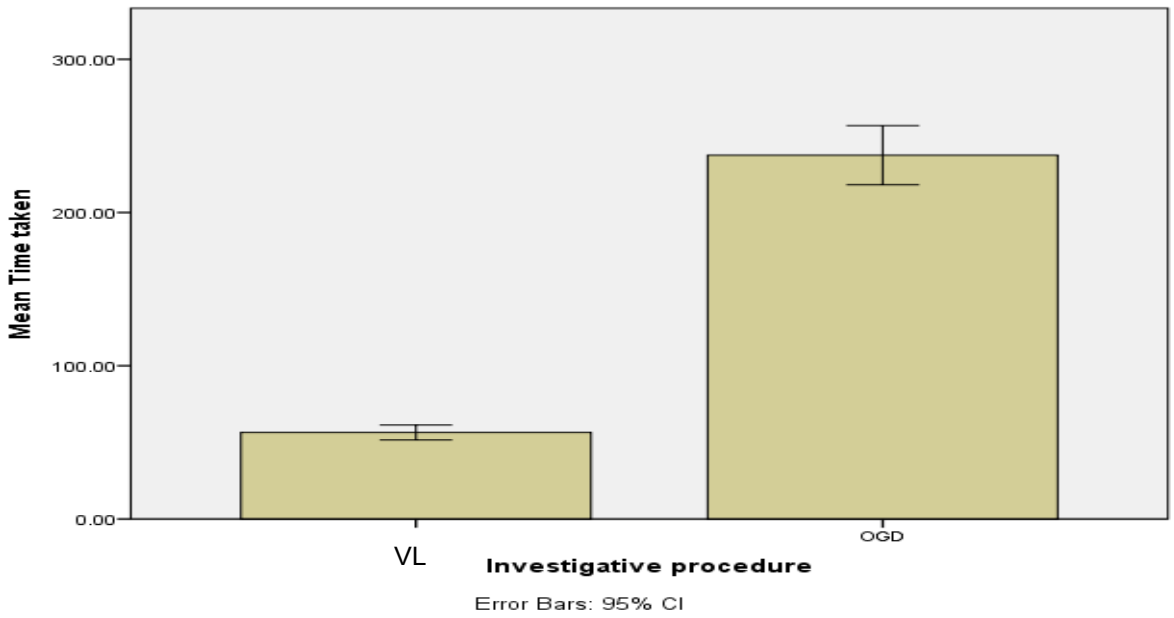


Figure 9: Comparing time taken for VL & OGD

Mean time taken for VL was significantly shorter compared to OGD, 56.5± 24.8 versus 237.4±106.4, **P<0.001** as shown in figure 9 above.

4.5 Comparison of Findings in Oesophagogastroduodenoscopy and Video Laryngoscopy

4.5.1 Comparison by Sub-Site

Univariate analysis with chi squared test revealed a significantly higher odds of VL in diagnosing abnormalities of the oropharynx [OR: 57(95%CI: 4.2-766.9), **P=0.006**], Larynx [OR: 44.3(95%CI:8.6-136.7), **P<0.0001**], and hypopharynx [OR: 33.4(95%CI: 9.6-62.3), **P<0.001**] compared to OGD in the same sub sites as shown in table in table 2 below.

Table 2: Comparison of VL and OGD by sub-site

Subsite	**VL**		**OGD**		**Odds Ratio**	**95% CI**	**P-value**
	Normal	Abnormal	Normal	Abnormal			
Oropharynx	115	6	117	4	57	4.2-766.9	**0.006**
Larynx	84	37	104	17	44.3	8.6-136.7	**<0.001**
Hypopharynx	104	17	115	6	33.4	9.6-62.3	**<0.001**

4.5.2 Agreement between Video Laryngoscopy and OGD

Cohen's κ analysis was run to determine if there was agreement between both investigative modalities in diagnosing abnormalities in the oropharynx, larynx, and hypopharynx. There was moderate agreement between both modalities in the oropharynx and larynx [κ=0.43(95% CI: -0.02-0.88), **P=0.006** and **κ**=0.59 (95%CI: 0.27-0.90, **P<0.001)** respectively] and hypopharynx, **κ**=0.57(95%CI: 0.21-0.83, **P<0.001).**

4.5.3 Sensitivity and Specificity of OGD

Table 3: Cross classification table

	VL			
		Abnormal	Normal	**Total**
OGD	Abnormal	26	7	**33**
	Normal	15	73	**88**
	Total	**41**	**80**	**121**

Table 4: Sensitivity and specificity of OGD

Parameter	**Value**	**95% CI**
Sensitivity	63.4%	46.9-77.4
Specificity	91.3%	82.3-96.1
Positive Predictive Value	78.9	60.6-90.4
Negative Predictive Value	83.0%	73.1-90.0
True positive rate	78.9	60.6-90.4
False positive rate	21.2%	9.6-40
True negative rate	83.0%	73.1-90.0
False negative rate	17.7%	10.3-27.5

The sensitivity and specificity of OGD was investigated with respect to video laryngoscopy as a gold standard. OGD was shown to be 63.4% sensitive and 91.3% specific in diagnosing pathologies of the various subsites, with positive and negative predictive values of 78.9% and 83.0 % respectively as shown in table 4 above.

4.5.4 Accuracy of OGD

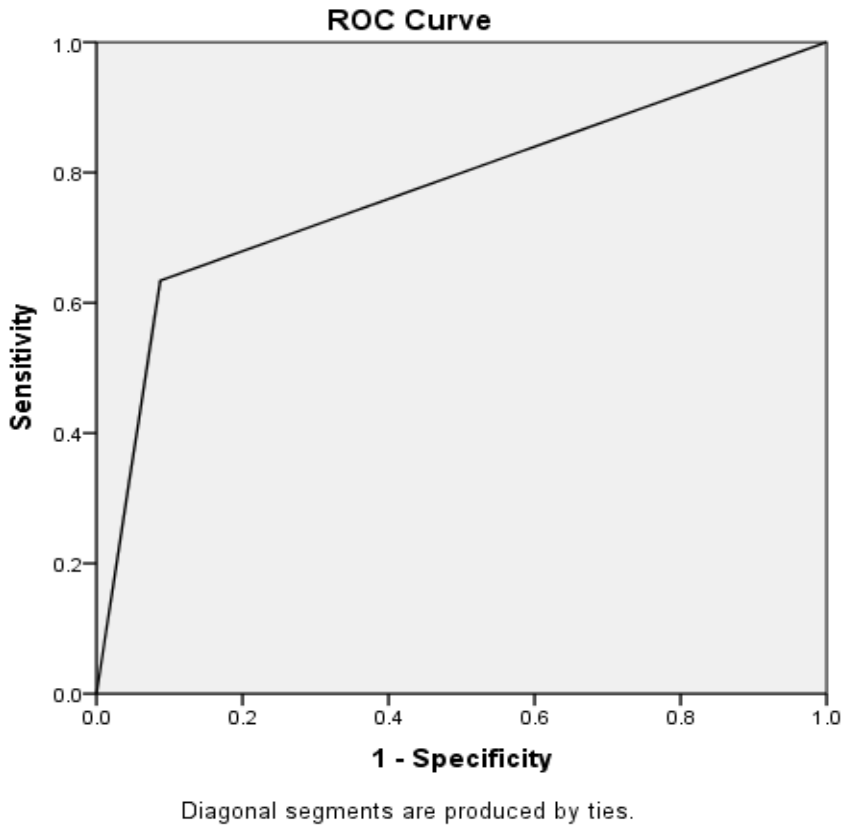


Figure 10: Receiver operator curve characteristics for OGD

The area under the curve is 0.77 showing acceptable accuracy of OGD as shown in figure 10 above.

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION & RECOMMENDATIONS

5.1 Discussion

OGD is one of the commonest diagnostic procedures done on the upper aero-digestive tract. Studies done have showed up to 5.4 % of all endoscopic upper gastrointestinal examinations have shown abnormalities in the laryngeal and pharyngeal regions.[17] In our study, 17.35% patients were found to have abnormalities in the laryngeal and pharyngeal areas during OGD. On video laryngoscopy, 25.61% were found to have laryngeal and pharyngeal abnormalities. This shows that OGD picked less pathologies compared to video laryngoscopy. Stephens et al [17]had 5.4% abnormalities on OGD picked in his study while Katsinelos et al had 3.89% abnormalities on OGD in his study. Lehman et al found 3.5% abnormalities in his participants. Our study found more abnormalities in the laryngeal and pharyngeal regions compared to other studies probably because of the health seeking behavior in our setting whereby patients tend to present to hospital when the symptoms of a disease become severe. Our study was also done at Kenyatta national hospital which is a tertiary hospital and the biggest referral hospital in Kenya and this could also explain the likelihood of picking more pathology in our setting.

According to this study, the commonest OGD finding was vocal cord paralysis at 5.6%, LPR at 4.96%, leukoplakia at 2.4%, vocal cord polyps and oropharyngeal candidiasis each at 0.8%. Lehman et al[16] did an examination of the larynx and pharynx and found 62% had chronic laryngitis, 20% had vocal cord paralysis and 5% had leukoplakia. Mullhaupt et al [15] found the commonest pathologies were chronic laryngitis, retension cyst then reinke's oedema. The findings of our study were different from the aforementioned studies. Our study had 121 participants while the mullhaupt et al had 1209 participants. This could explain the differences in terms of the lesions observed in the different populations that were studied.

Video laryngoscopy revealed that laryngopharyngeal reflux was the commonest abnormality found at 10.79% in our study followed by vocal cord paralysis at 8.33 % then laryngeal leukoplakia at 2.49%. Our study used a reflux finding score of above seven to make diagnosis of LPR but it is important to note that there is no consensus on standardized criteria that should be used to make the diagnosis. One patient with a laryngeal mass had a biopsy taken later that showed histology of a moderately differentiated squamous cell carcinoma. In the hypopharynx features of LPR were seen in 8.33% of the participants and one patient had a hypopharyngeal mass which later showed well differentiated squamous cell carcinoma on

histology. The hypopharyngeal mass was missed on OGD possibly due to the differences in the specifications of scopes used for examination in each modality and the inter-observer variations that may also have occurred. The commonest abnormality found in the oropharynx was tonsillar hypertrophy at 3.2%. This was also missed during OGD probably due to knowledge gap in terms of the Brodsky grading for tonsillar hypertrophy. One retroviral disease patient was found to have Kaposi like lesions in the oral cavity, oropharynx and larynx. Heartburn was the commonest presenting complaint in 31.4% of our participants, majority of who were diagnosed with gastroesophageal reflux disease (GERD) on OGD or chronic gastritis on OGD. Vocal cord paralysis was the second most common abnormality arising from oesophageal and thyroid malignancies. Video laryngoscopy is the gold standard for examination of the laryngeal and pharyngeal areas and therefore it has a significantly high likelihood of demonstrating pathology as demonstrated in our study.

A comparison of findings in OGD and video laryngoscopy (VL) showed that there was moderate agreement between both modalities in evaluation of the oropharynx (Cohen's k=0.43) and larynx (k=0.59) and the hypopharynx (k=0.57). P values of 0.006, <0.001, <0.001 for the oropharynx, larynx and hypopharynx respectively were statistically significant when comparisons between OGD and VL were made. Cammorata et al[(14)] had a kappa of 0.89 which showed an almost perfect agreement. The OGD missed a hypopharyngeal mass while the VL picked it probably due to the differences in the endoscopes that were used in each different investigative modality. Inter-observer variations could also have occurred making diagnosis of some pathologies subjective. A difference in anatomical positioning between the two endoscopic modalities may slightly alter the appearance of the piriform sinus more so when a mass is small or located submucosally. A lack of a template to offer guidance in terms of examination and reporting could also have contributed to this omission.

The sensitivity and specificity of OGD was investigated with respect to video laryngoscopy as a gold standard. OGD was shown to be 63.4% sensitive and 91.3% specific in diagnosing pathologies of the various subsites, with positive and negative predictive values of 78.9% and 83.0% respectively. Katsinelos et al[(27)] found that OGD was 84.6 % sensitive,100% specific with a positive predictive value(PPV) of 100% and a negative predictive value(NPV) of 99.2%.

Our findings were very different from Katsinelos study because of differences in methodology. Our study had one principal ENT investigator who relied fully on video laryngoscopy to examine all the patients unlike the Katsinelos et al[27] study who had 2 ENT surgeons who reviewed the video tapes and then gave independent diagnosis. The results of our study are more reliable because consistency was maintained. Mullhaupt et al[15] found a PPV of 43% and a NPV of 100% and Raju et al[28] had a PPV of 42% and a NPV of 100%. Our study had a different NPV compared to these studies and our PPV was higher than the Raju and Mullhaupt studies and this was probably because our study had one principal investigator examine all the patients physically while the aforementioned studies had the ENT surgeons reviewed video tapes in some patients and then examined some patients physically themselves without relying on a pre-recorded video tape.

In terms of time taken to evaluate the laryngeal and pharyngeal regions, our study took a mean time of 43 seconds with a time ranging from 7 to 108 seconds. The time taken for evaluation of some participants was longer due to the fact that some of our endoscopists were fellows undergoing training in gastroenterology and therefore the learning curve was different when compared to experienced gastroenterologists. The total OGD procedure took a mean time of 237 seconds. In our study, timing of the total OGD procedure was not done at the beginning before starting the study to actually have a baseline of how long the endoscopists take to do the OGDs routinely. This would have probably showed that the timings could be even shorter than the mean of 43 seconds that we recorded. The 43 seconds was within the time range of 30 to 108 seconds seen in Lehman et al and Saito et al studies [16,18]. We noted that it only takes an additional 43 seconds to evaluate these regions above the oesophageal opening and this could be beneficial in early detection of pre-cancerous lesions as well as other laryngeal and pharyngeal lesions in patients undergoing elective OGD.

5.2 Conclusion

Our study found that the diagnostic yield of laryngeal and pharyngeal pathologies during elective OGD was statistically significant. Pre-cancerous lesions like leukoplakia can be diagnosed on OGD. Additionally, Pathologies in the laryngeal and pharyngeal regions can be identified by adding an average of 43 seconds to total OGD procedure time. Laryngopharyngeal and upper GI symptoms overlap in patients and therefore OGD can be a useful adjunct in diagnosing laryngeal and pharyngeal pathologies. In conclusion, laryngeal and pharyngeal regions should be evaluated and the findings documented in the routine OGD reports.

5.3 Study Limitations

The reflux finding score used to diagnose LPR is very subjective and therefore different scores maybe given by different observers who are examining the same patient. RFS is used as a preliminary diagnostic tool and it has a low specificity of 37.5% and sensitivity of 87.8% and therefore could not be relied on fully without confirming the diagnosis with a 24hr PH probe monitoring test.

5.4 Recommendations

We recommend that laryngeal and pharyngeal findings to be added to the routine OGD reporting which could be captured in a revised standardized template. Additionally, otolaryngologists can train the endoscopists on identification of laryngeal and pharyngeal lesions. Otolaryngologists can also be trained to perform upper GIT endoscopies as these regions are familiar to them as well.

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TIMELINE

	Nov.2018-Feb 2019	March 2019	April-Sept 2019	Oct –Jan 2020	Feb-July 2020	Aug-Dec 2020	Jan-March 2021
Development of proposal							
Presentation to ENT dept.							
Corrections and dept.input							
Ethics approval							
Data collection							
Analysis							
Final presentation & submission							

BUDGET

ITEM	COST(KSH)
Statistician	20000
Stationery	35000
Research assistant	10000
Pioneer universal 70 degree laryngoscope	70000
Video flash disk	10000
Timer	10000
TOTAL	150000

APPENDICES

Appendix I: General Patient Information Form and Consent Form (English Version)

My name is Dr Loise Nyawira Warugongo. I am the principal researcher in this study. The study has been approved by the KNH/UON Ethics and Research Committee.

I am conducting a study entitled "**THE DIAGNOSTIC YIELD OF LARYNGEAL AND PHARYNGEAL SCREENING EXAMINATION DURING ROUTINE UPPER GASTROINTESTINAL ENDOSCOPY AT KNH: A COMPARISON BETWEEN INDIRECT LARYNGOSCOPY AND OESOPHAGOGASTRODUODENOSCOPY FINDINGS"**

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. 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

How you will participate?

a) I will ask you questions regarding your current complains and the history of your condition
b) I will carry out a complete Ear, Nose, Throat, Head and Neck examination.
c) Evaluation of your upper aero digestive tract will be done using a camera and a scope at the endoscopic unit in KNH
d) You will incur no extra financial costs and the confidentiality will be maintained at all times.

e) There will be no monetary benefits for participating in the study and it will be purely on a voluntary basis.

f) You will be informed about investigations and importance of the results.

g) You will reserve the right to withdraw from the study at any time without discrimination

Are there any risks involved?

There are no known risks anticipated in your participation in this study.

Is there any penalty for refusing to participate in the study?

No, there are no penalties and the patient will receive treatment as prescribed

What benefits will I get for participating in the study?

Any abnormalities found in the throat will be attended to by an ENT specialist.

What about confidentiality?

All the information that we obtain will be kept confidential.

Are there any extra costs involved?

There are no extra costs involved in the participation in this study. The patient will however be subject to any standard fees charged by the Kenyatta National Hospital as part of their management.

Are you satisfied with the information provided?

In case of any questions or inquiries, contact the following:

A. **Principal Investigator:**

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Patient study number: ……

Consent by patient:

I…….of……do hereby give consent to be included in this study on evaluation of the diagnostic yield of laryngeal and pharyngeal screening examination during routine upper gastrointestinal endoscopy at Kenyatta national hospital endoscopic unit.

The nature of the study has been explained to me by the doctor.

I Dr……..confirm that I have explained to the patient the nature of the study.

Date……..Signed…….

Thumb print for illiterate participant

Patient /next of kin:

Date ……Signed …….

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Kenyatta National Hospital.

If you have any questions on your rights as a participant contact the *Kenyatta National Hospital/UON- Ethics and Research Committee (KNH/UON-ERC)* by calling *2726300 Ext. 44355*.

Appendix II: General Patient Information Form and Consent Form (Swahili Version)

Fomu ya maelezo:

Utangulizi

Mimi ni daktari Loise Nyawira Warugongo. Mimi ni mwanafunzi katika idara ya upasuaji wa maskio, pua na koo. Ninakuomba idhini yako kushiriki katika utafiti huu

Utashiriki jinsi gani

a) Nitakuuliza maswali kuhusu malalamiko yako ya sasa na historia ya hali yako
b) Nitapima hali ya ugonjwa wako wa kichwa na shingo
c) Picha ya shingo na tumbo itafanywa katika idara ya endoscopy
d) Hutakuwa na gharama za ziada za kifedha na usiri utahifadhiwa wakati wote
e) Hakutakuwa na faida ya fedha kwa ajili ya kushiriki katika utafiti na itakuwa tu kwa msingi wa hiari.
f) Utatambuliwa kuhusu uchunguzi na umuhimu wa matokeo.
g) Utakuwa na haki ya kujiondoa kwenye utafiti wakati wowote bila ubaguzi.

Kushiriki kutakuathirije?

a) Utafiti huu hautakuathiri kwa njia yoyote

Kuna hatari yoyote katika ushiriki wako au kutoshiriki kwako?

a) Hakuna
b) Kukataa kushiriki katika utafiti huu hautaathiri ubora wa huduma utakayopokea.

Tutafanya nini na habari tutakayopata

Tutashiriki matokeo yetu na watu wengine kufanya masomo sawa na tunaweza kuchapisha matokeo yetu katika magazeti ya kisayansi au kuwasilisha katika mikutano ya kisayansi. Usiri wa wagonjwa wote utahifadhiwa.

Je, unastahili na taarifa iliyotolewa?

Ikiwa umeridhika na ufafanuzi wetu na uko tayari kushiriki, basi tafadhali saini fomu ya ridhaa hapa chini.

Sehemu ya Pili: Fomu ya Makubaliano

Numbari ya utafiti: ……

Kibali cha utafiti:

Mimi Bi/Bwana…… nimekubali kushiriki katika utafiti huu. Sahihi yangu ni thibitisho ya kwamba nimeelewa umuhimu wa utafiti huu na kwamba habari yoyote nitakayotoa itawekwa siri.

Tarehe……Sahihi ……...

Alama ya Kidole ya asiyeweza kuandika

Mimi daktari …… nadhibitisha ya kwamba nimeeleza mgonjwa kuhusu utafiti huu.

Tarehe ……..Sahihi……..

Mtafiti Mkuu:

Daktari Loise Nyawira Warugongo

Mwanafunzi wa upasuaji wa masikio,mapua na koo,

Chuo kikuu cha Nairobi,

Simu : 0723336958

Barua pepe:loisewarugongo@gmail.com

Wasimamizi:

Daktari Joyce Aswani

Daktari wa upasuaji wa Masikio, mapua na koo

Idara ya upasuaji,

Chuo kikuu cha Nairobi,

Daktari Musa Kipingor

Daktari wa upasuaji wa Masikio, mapua na koo

Idara ya upasuaji,

Hospitali kuu ya Kenyatta

Daktari Onyango Ayo

Daktari mkuu wa endoscopic unit

Hospitali kuu ya Kenyatta

utafiti yanaweza kutumwa kwenye *Kenyatta National Hospital/UON- Ethics and Research Committee (KNH/UON-ERC)* by numbari *2726300 Ext. 44355*.

Appendix III: Data Collection Sheet

Study No:-

1. Socio-demographic data

i. Age……

ii. Gender……..

iii. Smoking: YES/NO

   a. If yes number of pack years……

iv. Alcohol intake :YES/NO

   a. If yes type of brew and duration:……...

   b. Quantity:……..

2. Presenting complaints

- Dysphagia……..YES…….NO……
- Odynophagia……..YES……NO……
- Hoarseness of voice……YES……NO……
- Hawking……..YES……NO……
- Globus sensation……..YES……NO……
- Heartburn/ reflux…….YES…….NO……
- Others……..Specify……..
- None …….YES…….NO……

3. Examination findings (including Rigid laryngoscopy exam)

	NORMAL	**ABNORMAL (specify)**
Oral cavity:		
Dentition	☐	☐
Tongue –Ant. 2/3	☐	☐
Buccal mucosa	☐	☐
Hard palate	☐	☐
Oropharynx		
Tonsils	☐	☐
Soft palate	☐	☐
Base of tongue	☐	☐
Rt vallecula	☐	☐

Lt vallecula	☐	☐
Posterior pharyngeal wall	☐	☐
Rt Lateral oropharyngeal wall	☐	☐
Lt lateral oropharyngeal wall	☐	☐

Larynx

Lingual epiglottis	☐	☐
Laryngeal epiglottis	☐	☐
Rt aryepiglottic fold	☐	☐
Lt aryepiglottic fold	☐	☐
Rt arytenoid	☐	☐
Lt arytenoid	☐	☐
Rt false vocal cords	☐	☐
Lt false vocal cord	☐	☐
Rt true vocal cord	☐	☐
Lt true vocal cord	☐	☐
Anterior commissure	☐	☐
Posterior commissure	☐	☐

Hypopharynx

Rt piriform sinus	☐	☐
Left piriform sinus	☐	☐
Post-cricoid region	☐	☐
Posterior pharyngeal wall	☐	☐

Clinical impression

.....

4. FINDINGS DURING OGD:

	NORMAL	**ABNORMAL (specify)**
OROPHARYNX		
Tonsils	☐	☐…….
Soft palate	☐	☐…….
Base of tongue	☐	☐…….
Rt vallecula	☐	☐…….
Lt vallecula	☐	☐…….
Posterior pharyngeal wall	☐	☐…….
Rt Lateral oropharyngeal wall	☐	☐…….
Lt lateral oropharyngeal wall	☐	☐…….

Normal oropharynx ……YES…….. NO…….(go to table below).

If not normal Please ticks the Lesion suspected clinically and indicate specific site/side where applicable:

OROPHARYNGEAL LESIONS	Tick if lesion seen	OGD FINDINGS	IL FINDINGS
Oropharyngeal candidiasis			
Leukoplakia			
Erythroplakia			
Erythroleukoplakia			
Apthous ulcers			
Oropharyngeal CA			
Others (specify)			

	NORMAL	**ABNORMAL (specify)**
LARYNX		
Lingual epiglottis	☐	☐……..
Laryngeal epiglottis	☐	☐……..
Rt aryepiglottic fold	☐	☐……..
Lt aryepiglottic fold	☐	☐…….
Rt arytenoid	☐	☐…….
Lt arytenoid	☐	☐…….
Rt false vocal cord	☐	☐…….

Lt false vocal cord ☐ ☐…….

Rt true vocal cord ☐ ☐…….

Lt true vocal cord ☐ ☐……..

Anterior commissure ☐ ☐……..

Posterior commissure ☐ ☐……..

Normal larynx ……YES……. .NO……..(go to table below)

If not normal Please ticks the Lesion suspected clinically and indicate specific site/side where applicable:

LARYNGEAL LESIONS	OGD FINDINGS TICK IF LESION SEEN	LEFT	RIGHT	IL FINDINGS
Vocal cord polyps				
Vocal cord nodules				
Vocal cord paralysis				
Vocal cord hemorrhage				
Reinkes oedema				
Presbylaryngis				
LPR				
Laryngeal papillomatosis				
Laryngitis				
Laryngitis sicca				
Unilateral Vocal cord paralysis				
Bilateral vocal cord paralysis				
Leukoplakia				
Laryngeal CA				
Laryngopharyngeal reflux (refer to reflux finding score)				
Others (specify)				

NORMAL **ABNORMAL (Specify)**

HYPOPHARYNX

Rt piriform sinus ☐ ☐……..

Left piriform sinus ☐ ☐……..

Post-cricoid region ☐ ☐……..

Posterior pharyngeal wall ☐ ☐……..

Normal hypopharynx ……..YES……...NO……(go to table below)

HYPOPHARYNGEAL LESION	TICK IF LESION SEEN	OGD FINDINGS	IL FINDINGS
Hypopharyngeal candidiasis			
Pharyngeal papillomatosis			
Hypopharyngeal CA			
Others (specify)			

Biopsy taken:

Yes ……Specify ……

No …...Specify (Why not?)……

Histology results ……

2. **Level of training (go to table below)**

……

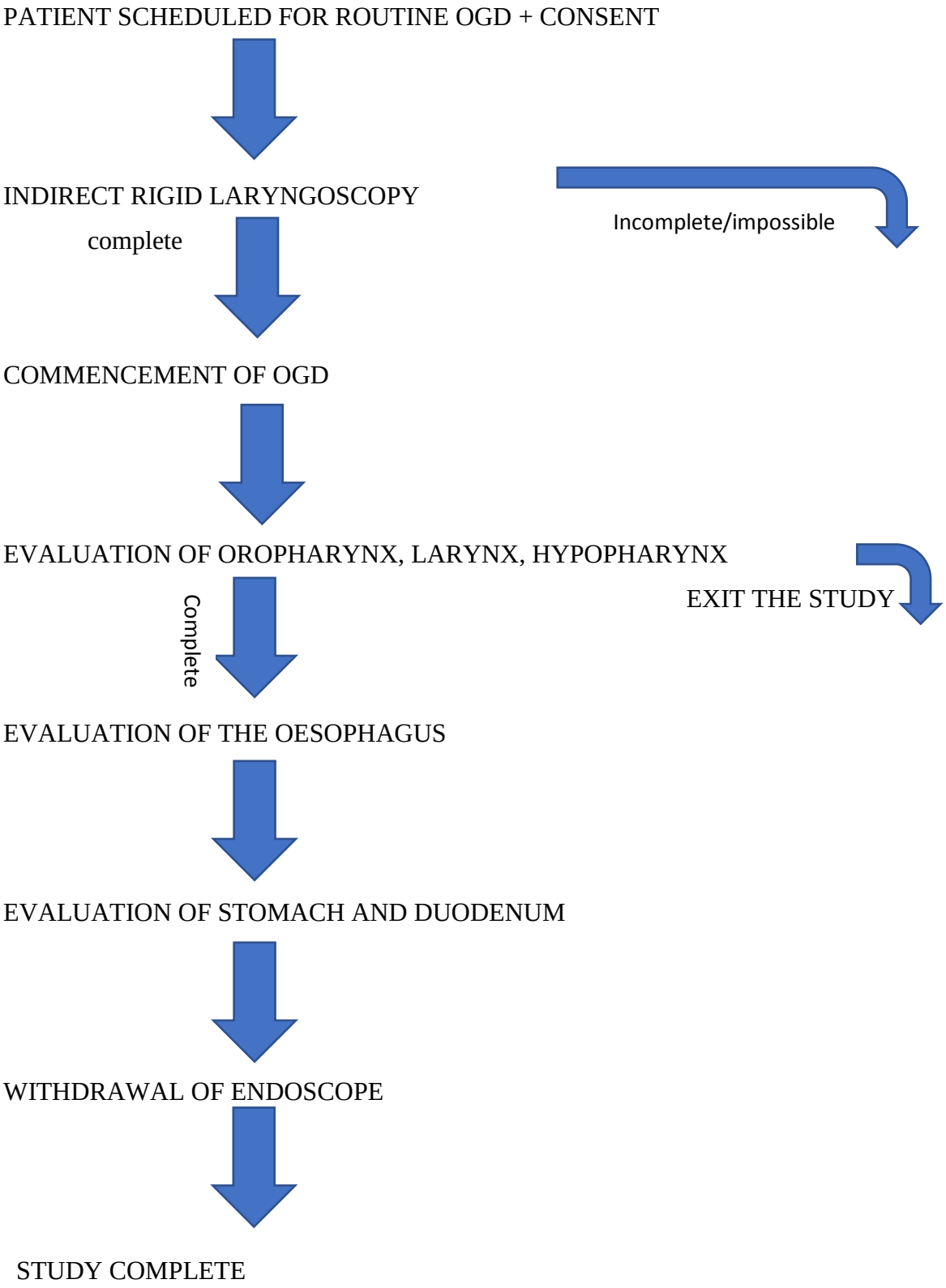
ENDOSCOPIST	**DEPARTMENT**	**YEAR OF STUDY**
REGISTRA		
		YEARS OF EXPERIENCE IN ENDOSCOPY(Tick where appropriate)
CONSULTANTS		<5
		5-10
		11-15
		>15

TIME TAKEN DURING OGD

From oropharynx to opening of the oesophagus ……

From oropharynx to complete evaluation of the duodenum ……

Appendix IV: Flow Chart



Appendix V: Pre-Screening Tool

STUDY NO:

DATE OF BIRTH:

	YES	**NO**
ARE YOU SCHEDULED FOR OGD TODAY?		
IS IT AN ELECTIVE OGD?		
IS IT AN EMERGENCY OGD?		
ANY ALLERGY TO LIDOCAINE?		
ANY PREVIOUS NECK, LARYNGEAL OR PHARYNGEAL SURGERY?		
IS THE PATIENT STABLE ENOUGH TO UNDERGO OGD?		
ANY SIGNS OF IMPENDING UPPER AIRWAY OBSTRUCTION?		
ANY PREVIOUS RADIOTHERAPY IN THE HEAD AND NECK REGION?		

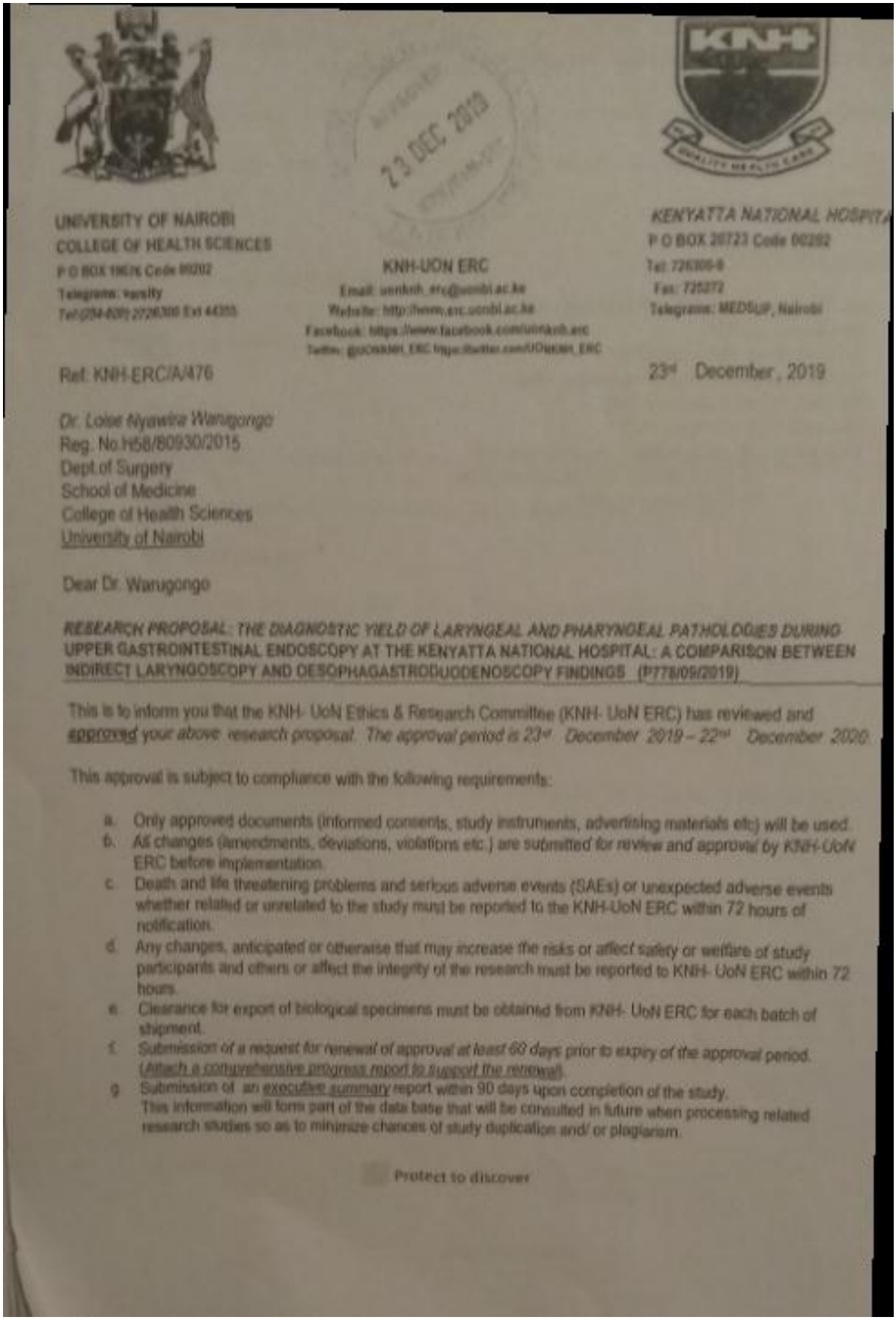
Appendix VI: Reflux Finding Score

Reflux Finding Score

Subglottic Edema	2 = present 0 = absent	
Ventricular Obliteration	2 = partial 4 = complete	
Erythema/Hyperemia	2 = arytenoids only 4 = diffuse	
Vocal Fold Edema	1 = mild 2 = moderate 3 = severe 4 = polypoid	
Diffuse Laryngeal Edema	1 = mild 2 = moderate 3 = severe 4 = obstructing	
Posterior Commissure Hypertrophy	1 = mild 2 = moderate 3 = severe 4 = obstructing	
Granuloma/Granulation	2 = present 0 = absent	
Thick Endolaryngeal Mucus	2 = present 0 = absent	
	Total:	

Source: Center for Voice Disorders of Wake Forest University. Reprinted with permission.

Appendix VII: KNH/UoN-ERC Letter of Approval



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Ref: KNH-ERC/A/476

23rd December, 2019

Dr. Loise Nyawira Warugongo
Reg. No.H58/80930/2015
Dept.of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Warugongo

RESEARCH PROPOSAL: THE DIAGNOSTIC YIELD OF LARYNGEAL AND PHARYNGEAL PATHOLOGIES DURING UPPER GASTROINTESTINAL ENDOSCOPY AT THE KENYATTA NATIONAL HOSPITAL: A COMPARISON BETWEEN INDIRECT LARYNGOSCOPY AND OESOPHAGASTRODUODENOSCOPY FINDINGS (P778/09/2019)

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 23rd December 2019 – 22nd December 2020.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. 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.
d. 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.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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).
g. Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

Appendix VIII: Similarity Index

THE DIAGNOSTIC YIELD OF LARYNGEAL AND PHARYNGEAL PATHOLOGIES DURING UPPER GASTROINTESTINAL ENDOSCOPY AT THE KENYATTA NATIONAL HOSPITAL: A COMPARISON BETWEEN INDIRECT LARYNGOSCOPY AND OESOPHAGOGASTROD

by Dr.loise Nyawira Warugongo

Dr. Aswani J. M.

THE DIAGNOSTIC YIELD OF LARYNGEAL AND PHARYNGEAL PATHOLOGIES DURING UPPER GASTROINTESTINAL ENDOSCOPY AT THE KENYATTA NATIONAL HOSPITAL: A COMPARISON BETWEEN INDIRECT LARYNGOSCOPY AND OESOPHAGOGASTROD

ORIGINALITY REPORT

9%	5%	5%	3%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	B Mullhaupt. "Controlled prospective evaluation of the diagnostic yield of a laryngopharyngeal screening examination during upper gastrointestinal endoscopy", Gut, 2004 Publication	1%
2	erepository.uonbi.ac.ke:8080 Internet Source	1%
3	Submitted to University of Dundee Student Paper	1%
4	erepository.uonbi.ac.ke Internet Source	1%
5	Merati, A.L.. "Normal endoscopic anatomy of the pharynxand larynx", The American Journal of Medicine, 20030818 Publication	1%

Dr. Aswani J. M.