

**NUTRITIONAL STATUS AMONG HEAD AND NECK CANCER
PATIENTS AT MUHIMBILI NATIONAL HOSPITAL**

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**MMed (Otorhinolaryngology) Dissertation
Muhimbili University of Health and Allied Sciences
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Muhimbili University of Health and Allied Sciences
Department of Otorhinolaryngology



**NUTRITIONAL STATUS AMONG HEAD AND NECK CANCER
PATIENTS AT MUHIMBILI NATIONAL HOSPITAL**

By

Peter Nyakubega

**A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of
Master of Medicine (Otorhinolaryngology) of**

**Muhimbili University of Health and Allied Sciences
October, 2021**

CERTIFICATION

The undersigned certify that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; **“Nutritional Status among Head And Neck Cancer Patients at Muhimbili National Hospital”** in (partial) fulfillment of the requirements for the Degree of Master of Medicine (Otorhinolaryngology) of Muhimbili University of Health and Allied Sciences.

Dr. Enica Richard

(Supervisor)

Date

DECLARATION AND COPYRIGHT

I, **Peter Nyakubega**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

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DEDICATION

I dedicate this work to my beloved deceased parents Daniel Nyakubega and Theopista Bihemo whom instilled me with the spirit of hard work and lot other good qualities.

To my wife Mshinwa Mtango for her love and care to me and to our children

To My lovely sons and daughter Daniel, Kiariro, and Nyanjura who tolerated a lot my absence in completion of this work

ABSTRACT

Background: Studying nutrition in cancer patients is a challenging task. Some of the issues brought by this subject were related to socioeconomic status of patient which influences access to food. Therefore, before one concludes that cancer is the culprit to malnutrition one had to rule out access to food as a factor. Head and Neck region is involved with intake and initial processing of the food. Therefore, presence of tumor in any subsite has a direct effect on nutritional status of the patient. HNC has been shown to be associated poor nutritional status since the first presentation of patients to health facility.

Aim: This study aimed to establish nutritional adequacy among HNC patients accessing services at ENT department at MNH.

Materials and Methods: This was cross sectional descriptive involving all HNC patients attended at MNH ENT department from 1st August,2020 to 31st January,2021.The study collected background information about access to food i.e. with the use of Dietary Screening Tool(DST) and later nutrition was measured by anthropometric measurements(weight and height) and biochemical test(serum albumin levels).The later was used to compute Nutritional Risk Index obtained by the formula $\text{Nutritional Risk Index} = (1.519 \times \text{serum albumin, g/L}) + 0.417 \times (\text{present weight/usual weight} \times 100)$. A Nutritional Risk Index >100 indicated that the patient is not malnourished, 97.5–100 indicated mild malnourishment, 83.5-<97.5 indicated moderate malnourishment and <83.5 indicated severe malnourishment. After data collection the later was checked for correctness by running frequency tables and analyzed by SPSS version 26.

Results: The study involved a total of 113 participants. Age ranged from 15 to 93 years old with mean age of 51.81+/-17.439 years. There were 74 males and 39 female making a ratio of 1.9:1. Majority of participants were having Laryngeal tumor (46%), followed by sinonasal and Hypopharygeal tumor which made 24% and 15% respectively. Significant proportion of patients (85.6%) in the study had an advanced disease(Stage III& IV)+, with stage IV involving more than half of participants (52.2%).Stage I disease only involved 1.8% of

participants. About 17% of patients presented to MNH with a pre-existing dietary risk i.e. DST score of less than 60 points. This study found that 36.3% of patients had severe malnourishment at presentation as they scored less than 83.5 points based on NRI score. Highest percentage of malnutrition was found in Oropharyngeal tumor (75%), followed closely by Hypopharyngeal and Nasopharyngeal tumor each with 66.7%. The difference was however not significant ($\chi^2 = 27.577$ $P = .069$). Stage IV patients were severely malnourished in greatest percentages and this finding was significant (57.6%) $\chi^2 = 64.414$ $P = .000$

Conclusion: Laryngeal tumor has been shown to be more common in men and is much related to an advanced age. Most of patients with HNC had severe malnourishment at presentation. Poor nutrition prior to disease predisposes HNC patients to severe malnourishment during illness.

Recommendation: Health care practitioners should address patients with HNC tumors with care by providing adequate nutritional support as required. The public should have tendency to good dietary behaviors as this practice has impact on disease state. Again literature links good diet to promotion of immunity against various pathologies including HNC. There's a role of health practitioners and ministry of health to educate the public against late attendance to health facilities when the disease is at an advanced stage.

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LIST OF ABBREVIATIONS

BMI-	Body Mass Index
FFQ-	Food Frequency Questionnaire
HFIAS-	Household Food Insecurity Access Scale
IDDS-	Individual Dietary Diversity Score
NRI-	Nutritional Risk Index
TST-	Triceps Skinfold Thickness
HNC-	Head and Neck Cancer
HCW-	Health Care workers
TNNS-	Tanzanian National Nutritional Survey
ENT-	Ear Nose and Throat
MNH-	Muhimbili National Hospital
MUHAS-	Muhimbili University of Health and Allied Sciences
IRB-	Institutional Review Board
MMed-	Master of Medicine
DST-	Dietary Screening Tool
SPSS-	Statistical Package for the Social Sciences
HNSCC-	Head and Neck Squamous Cell Carcinoma
TNM-	Tumour, Node and Metastasis
PG-SGA-	Patient Generated Subjective Global Assessment tool
CWL-	Critical Weight Loss

DEFINITIONS OF TERMS

1. **Malnutrition** is defined as a nutritional status in which a deficiency in energy, protein, or other nutrients causes measurable adverse effects on tissues or body form, function, or clinical outcomes¹

2. **Food security**-is a state in which “all people at all times have both physical and economic access to sufficient food to meet their dietary needs for a productive and healthy life”²

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Subject of nutrition in cancer patients is often wide and impractical to be covered in its completeness in one study. Some of the factors affecting nutrition of patients are related to socioeconomic status of patient which influences access to food. So the moment patient is battling with the disease his/her nutrition status may also be affected by access factors

Presence of cancer has been incriminated for potentiating cachexia in patients. This is attributed for by factors grouped as either pro inflammatory or pro cachexia. Pro inflammatory factors released by tumors include IL-1, IL-6 and TNF- α . TNF- α is a cell signalling protein responsible for several metabolic derangements. TNF- α is released by activated macrophages and by many other types of cell such as CD4+, neutrophils, mast cells, eosinophils and neurons. TNF- α has a direct catabolic effect on skeletal muscle it also act by inducing Ubiquitin Proteasome System (UPS). UPS is the major intracellular protein degradation system. TNF- α has been shown to increase gluconeogenesis, proteolysis and loss of adipose tissue which brings about decreased glycogen synthesis, protein and lipid.(1)

A study by Llovera showed that TNF- α doubles the expression of ubiquitin gene leading to increased activity of Ubiquitin Proteasome System in skeletal muscles which leads to protein degradation and wasting.(2)

Another perspective in nutrition to head and neck cancer is the anatomical location of a disease. The head and neck region is so much involved with intake and initial processing of food. Presence of tumor in any of its subsite has significant influence on nutritional status of the patient.

Assessment of nutritional status is seen by majority of clinicians as something essential however the practice of nutritional assessment is poorly practiced. This has been evidenced by a local study done to health care workers at Morogoro by Moses H,2010.In this study it was

shown that only 17% of Health care workers practiced nutritional assessment regardless of the pathology. The same paper revealed that proper nutritional knowledge was lacking among clinicians (42%) which explained poor practice towards assessing patient nutritional status.

Nutritional assessment in cancer patients poses unique challenge especially for the bed ridden as physical measurements (anthropometric measurements) such as height and weight requires a patient to be on a standing position, however different alternatives to these measurements are available as it has been highlighted in the methodology section. In this particular study the use of biochemical measurement (Serum albumin) as an alternative parameter to nutritional assessment was employed. This study used a combination of two approaches (Biochemical and anthropometric measurement) as its minimum recommended for assessing nutrition.

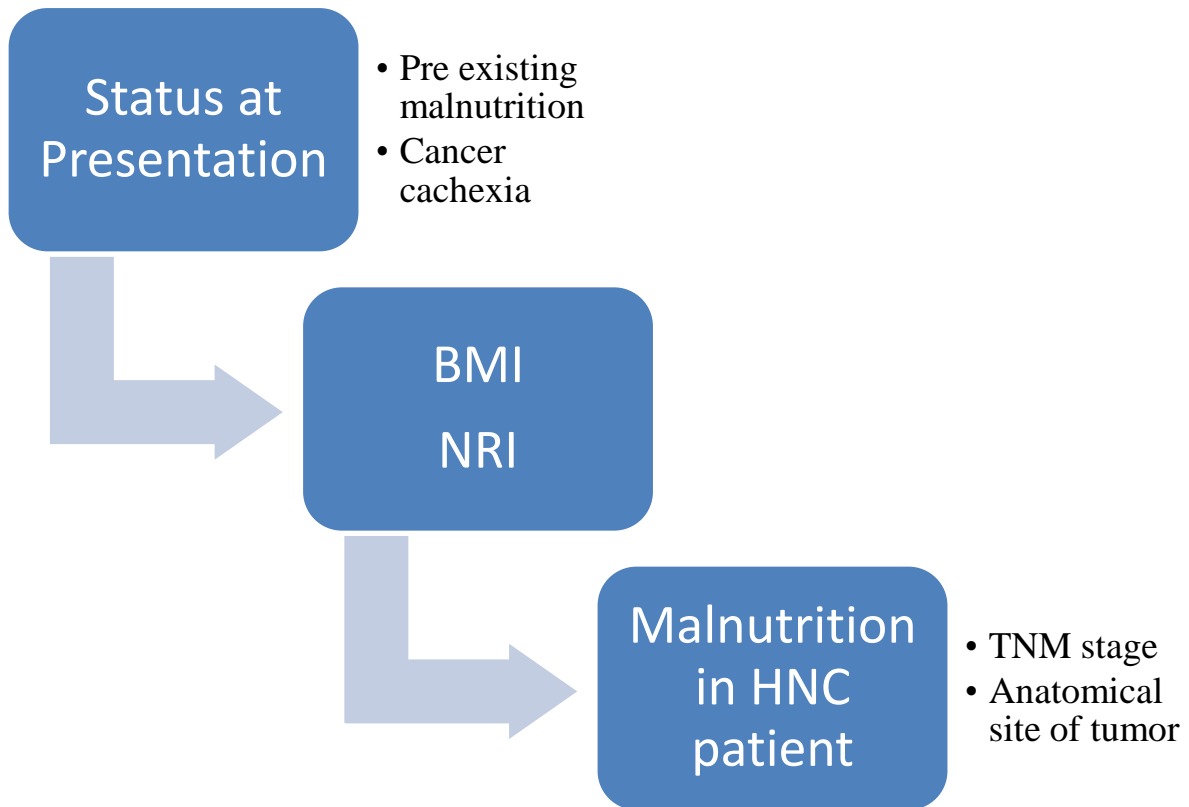
Malnutrition in head and neck cancer patient has been shown to have undesired outcomes such as poor immunity which result into prolonged morbidity and mortality in these patients (3).The same study also revealed poor treatment response on malnourished patients.

1.2 Problem statement

Nutritional status of cancer patient is a key parameter on influencing outcome of the disease like length of hospital stay, prognosis and the course of disease. Malnutrition in cancer patients is significant in some literature it's reported to be present in 35-60% of all head and neck cancer patients at the time of presentation(4). Malnutrition in head and neck cancer is a result of most cancers in the region to impair ability of oral intake. Again due to debilitating effects of the disease cancer patients often succumb to socioeconomic difficulties leading to poor access to food. This also affects the course of disease and overall nutrition of head and neck cancer patient.

There's an existing vacuum of knowledge on how malnutrition (regardless of its cause) affects head and neck cancer patient at the time they present to health facility. There's also evidence on how nutritional assessment in head and neck cancer is often neglected, seen as inappropriate or it's performed too late in the course of illness(5). The relationship between HNC cancer stage, site and how they affect nutrition status of patient is scarcely mentioned not only in local but global literature. This gap is relevant at Muhimbili National Hospital which is a snapshot of the country status at large. This study is intended to address this problem.

1.3 Conceptual framework



1.4 Rationale

This study will help Ministry responsible for Health, Stakeholders and ENT fraternity at large in addressing customized needs of head and neck cancer patients and therefore provide room for tailored therapies which address nutritional needs.

Again this study will shade some light on anatomical distribution of HNC and their relationship with malnutrition. Lastly the study has shaded some light on other non-tumor factors which impact the nutritional status of head and neck cancer patients.

1.5 Research Questions

1. What are the age and sex characteristics of different HNC at presentation in MNH
2. What proportion of HNC patients presents with malnutrition at diagnosis
3. What relationship exists between anatomical site of tumor and nutritional status
4. What relationship exists between tumor stage and nutritional status
5. How severe is the pre-existing nutritional risk in patient with HNC, if any

1.6 Objective

1.6.1 Broad Objective

To determine nutritional status among patients with H&N cancer attending ENT services at MNH

1.6.2 Specific objectives

1. To Determine age and sex characteristics of different HNC at presentation in MNH ENT department.
2. To Determine nutritional status of HNC at presentation in MNH ENT department
3. To Assess relationship of anatomical site of the tumor on nutritional status
4. To Assess relationship between tumor stage and nutritional status
5. To determine pre-existing nutritional risk in patient with HNC

1.7 Literature Review

Evidence shows that regardless of optimal cancer treatment offered, the patient with HNC will have poor prognosis if has a weight loss of more than 15 percent(6).The same literature explains that malnutrition is a cause of mortality in 5 to 25% of cancer patients(6).

1.7.1 Nutritional status of HNC patients at presentation

The HNC has been shown to cause poor nutritional status since presentation. Pile of evidence shows majority of HNC patients are malnourished at presentation , Gosak revealed up to 50% of HNC are malnourished at the time they present to seek care(7). They went on to describe the cause of this pattern as the decreased food intake and other psychological factors. Another work by Capuano(8) has shown that most of HNC patients presents with malnutrition even prior the commencement of treatment with 25-50% of HNC patient have malnutrition before any treatment.

1.7.2 Anatomical site of the tumor and nutritional risk

Anatomical site of tumor has influence on the risk for malnutrition. Amaral(9) in Portugal, found that tumors of head and neck region had higher nutritional risk as compared to other anatomical areas such as peritoneum, lymph ganglia and gastrointestinal cancer, however this study didn't show effect on nutrition among different sub sites of head and neck cancers.

Another study by Jha (10) in Canada went further and described impact of HNC on malnutrition comparing different head and neck sub sites and it revealed that Oral cavity and Pharyngeal cancers had more impact i.e.(27% and 34%) respectively as compared to other sites such as salivary glands and paranasal sinuses which had a prevalence of 8% and 4% respectively.

A contrasting evidence was produced by Takenaka (11) in Japan showed patients with HNC(Pharyngeal cancer) had no difference in nutritional status with the rest of population, he attributed this finding to advancement in endoscopic technology in Japan which facilitate early diagnosis of the tumor.

A study by Kaduka,(12) in Kenya shows that malnutrition was prevalent on cancer patient with Breast cancer bearing an Adjusted Odds Ratio of 0.3 and Lip, oral &pharyngeal cancer having AOR of 0.73 for malnutrition.

1.7.3 Tumor stage and malnutrition

A study by Takenaka (11) in Japan supported the knowledge that advance T stage in HNSCC has influence on poor nutritional status of patients however he didn't pointed out specific staging and effect on malnutrition. Another work by Kang(13) in China made a mention on how tumor stage affected nutritional status of HNC patient by didn't tell how specific stages have effects on nutrition. Hagjoo(5) also had a similar argument that tumor stage of HNSCC has effect on nutrition but couldn't explain the details of staging and corresponding malnutrition effects.

Again Kubrak in Canada had a description of how different tumor stage had impact on malnutrition and she showed that T1 and T2 staging in TNM had a comparable effect on malnutrition i.e. 24% while T4 had worse effect on malnutrition with prevalence of 27% at the time of diagnosis.

Gosak(14) reports that HNC presents with locally advanced disease in about more than two thirds of the cases seen in cancer centers. He attributed this presentation to poor socio economic status of these patients which is caused by excessive alcohol and cigarette consumption. Other evidence by Jatoi(15), indicated that preoperative malnutrition had poor effect on surgical outcome of patient with head and neck cancer but this study as many on this topic had no mention on the effect of cancer stage.

Kaduka(12) in Kenya had shown that malnutrition is diagnosed early in cancer patients with OR being higher in cancer stage II as compared to stage III(Stage IV being reference) she attributed this to socio economic factors surrounding cancer patients leading to early cachexia. These factors included but not limited to poor dietary diversity. However this study didn't make a specific mention of HNC but rather Breast and esophageal cancers

1.7.4 Pre-existing nutritional risk in Head and Neck Cancer patient

Poor nutritional status of cancer patient has not only been shown as an outcome but also a risk on its own. It's documented that patients who are undernourished have higher risk of developing head and neck cancer (5).The same risk is posed by overweight and obesity however the later carries more risks such as disease recurrence and poor survival(5).

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study design

Hospital based cross sectional descriptive study.

2.2 Study Population

All head and neck cancer patients attended at Muhimbili National Hospital ENT department from 1st August 2020 to 31st January, 2021. The study included patients aged 15years and above, attended due to head and neck cancer at MNH ENT department.

2.3 Sample size and Sampling Technique

Sample size was obtained by estimations based on the following computation as proposed by Fischer sampling formula (16). Selection of participants will be determined by the stated inclusion criteria from HNC patients at MNH ENT clinic and wards

$$\text{Sample size}(n) = \frac{Z^2 P(100-P)}{\epsilon^2}$$

From the formula above

n=Sample size

Z=Confidence level at 95% (1.96)

P=Estimated prevalence (33.1%) Kaduka (12)

ϵ =Margin of error at 6%

Estimated sample size will therefore be

$$n = 1.96^2 \times 33.1 \times (100 - 33.1) / 6^2$$

Hence, the estimated sample size for this study was 120

2.4 Inclusion and Exclusion Criteria

2.4.1 Inclusion Criteria

All patients with HNC attended at Muhimbili ENT department from 1st January 2021 to 30th April 2021. Patients who were included were those with identified primary site of malignancy and those who have been staged clinically and diagnosis confirmed by histopathology.

2.4.2 Exclusion Criteria

Patients with Gastrostomy Feeding tube and Nasogastric tube Feeding were excluded from the study. Another group was excluded are those patients who had history of treatment (Chemotherapy, Surgery or radiotherapy) at the time they presented to MNH. Lastly those patients who did not consent for the study were excluded.

2.5 Variables

The variables which were tested in the study included nutritional status of different HNC at presentation, Age and Sex composition of HNC at presentation, Anatomical site of tumor versus nutritional status, Stage of the tumor versus nutritional status and pre-existing nutritional risk. Nutritional status of a patient is a dependent variable which depends on Anatomical site of tumor Stage of the tumor and pre-existing nutritional risk as independent variables.

2.6 Data collection methods

Data from patients were collected through three methods i.e. clinical interview, physical examination and laboratory work up. In the clinical interview dietary screening tool(DST)(See Appendix 1) was used, this tool is a simplified assessment tool which captures the main dietary components and it has been assigned score to 100 points, weight of each food category was assigned by dietary principal components analysis done in previous studies by Bailey(17).In each food category questions have been allotted scores based on factor load for each question. Total score for each patient were computed and the patient were categorized as having nutritional risk if they have a DST score of less than 60,possible risk if they have DST

score from 60-75 and those who scored above 75 were categorized as not having nutritional risk. This tool helped to distinguish the malnourishment attributed to by poor access/dietary behavior as contrasted to that due to disease process.

Again in clinical interview reference weight of the patient was sought by establishing weight of a patient 6 months prior diagnosis of cancer (6). For those who didn't recall their weight usual weight of a person was used instead. This was compared to the current weight to get the percentage of weight drop. Later on, the results of this assessment were subjected in the Nutritional Risk Screening tool (see appendix 3). In this tool overall nutritional risk was computed to know whether the patient is of Low, Medium or High nutritional risk and specific recommendations will be made. Other additional information which was sought for completion of nutrition risk screening will be illness status which may subject the patient into inability to eat for more than 5 days.

In physical examination, parameters which were assessed include Anthropometric measurements. The later included measurement of body weight and height which were used to compute Body Mass Index (BMI). BMI was computed by dividing body weight (in Kg) by the square of the height (in metres) and classified for adults: underweight if $BMI \leq 18.4 \text{ kg/m}^2$; normal weight if $18.5 \leq BMI \leq 24.9 \text{ kg/m}^2$; pre-obese if $25.0 \leq BMI \leq 29.9 \text{ kg/m}^2$ and obese if $BMI \geq 30.0 \text{ kg/m}^2$. For those patients who were unable to stand recumbent height was measured, backed by Lee & Nieman as cited in Amaral 2008(9).

Laboratory workup involved assessment of serum albumin. This biochemical parameter was used to compute Nutritional risk Index by the following formula $\text{Nutritional Risk Index} = (1.519 \times \text{serum albumin, g/L}) + 0.417 \times (\text{present weight/usual weight} \times 100)$. Nutritional risk index is a powerful screening tool which has been validated in various clinical settings for screening malnutrition in cancer patients(15). A Nutritional Risk Index >100 indicates that the patient is not malnourished, 97.5–100 indicates mild malnourishment, 83.5–<97.5 indicates moderate malnourishment and <83.5 indicates severe malnourishment. Serum albumin was measured from fasting blood levels.

2.7 Data validity and reliability

Validity of this study is drawn from the choice of instrument for measuring variables which are BMI and NRI which have been inferred to patient with different nutritional disorders with high accuracy. Reliability of the data was tested by inter tester variability as the data was collected by principal investigator together with an assistant who was trained on the study protocol using the same instruments. Again, reliability was tested by Test-retests technique in which variable such as height of a patient was tested and retested to same patient by the same investigator to monitor consistency of the results.

2.8 Data management

Data collected was handled by principal investigator together with research assistant. The former was responsible for entering the data from Questionnaires (Hard copies) to a computer program (IBM-SPSS verison 26).The questionnaires were handled in the same day of data collection to the principal investigator who captured the same data and remained with hard copies of questionnaire for reference until completion of the study. After that the hard copies (which bear no names) were shredded.

2.9 Data analysis

After collection the data was checked for correctness and manually entered to computer software SPSS version 26

Cleaning of data was done by running frequency tables, using SPSS. The missing items were sought out and entered to the right category. In this process the missing items were isolated and included in the data.

Cross tabulations were plot for Nutritional status of HNC versus Anatomical site of the tumor, Tumor stage, Status at presentation and Pre-existing nutritional risk. Relationship of the variables was tested by chi square tests.

2.10 Ethical Issues

Ethical clearance to conduct this study was sought from Muhimbili University of Health and Allied Sciences IRB and permission sought from MNH.

Principle of anonymity was highly observed in the conduct and reporting of this study and the participation to the study was on voluntary basis after verbal and written informed consent. Minors were given assent and their consents were signed by their legal caretakers.

2.11 Study Limitations

This study was limited by one of the tools used for data collection i.e. Dietary Screening Tool which had some food items that are not common in African setting. To overcome this we used the closest type of food to the one which is available in our local settings

CHAPTER THREE

3.0 RESULTS

3.1 Age and Sex characteristics of participants

A study involved 113 participants with age ranging from 15 to 93 years old, mean age was 51.81 \pm 17.439 years. Three age groups based on WHO stratification were employed i.e. 15-47 years (young adults), 48-63years (Middle aged) and above 64(as Elderly people).Majority were in the age group 48-63 years (41.6%) of all participants. There were 74 males and 39 female making a ratio of 1.9:1.

Table 1: Age and Sex distribution (N=113)

Variable	n(%)
A. Age group(years)	
15-47Young adults	40(35.4)
48-63 Middle Aged	47(41.6)
=/>64 Elderly	26(23)
B.Sex	
Male	74(65.5)
Female	39(34.5)
Total	113(100)

3.2 Tumor site distribution

Majority of participants had Laryngeal tumor (46%), followed by sinonasal and Hypopharyngeal tumor which made 21.2% and 13.3% respectively. Nasopharyngeal had the least participants (2.7%)

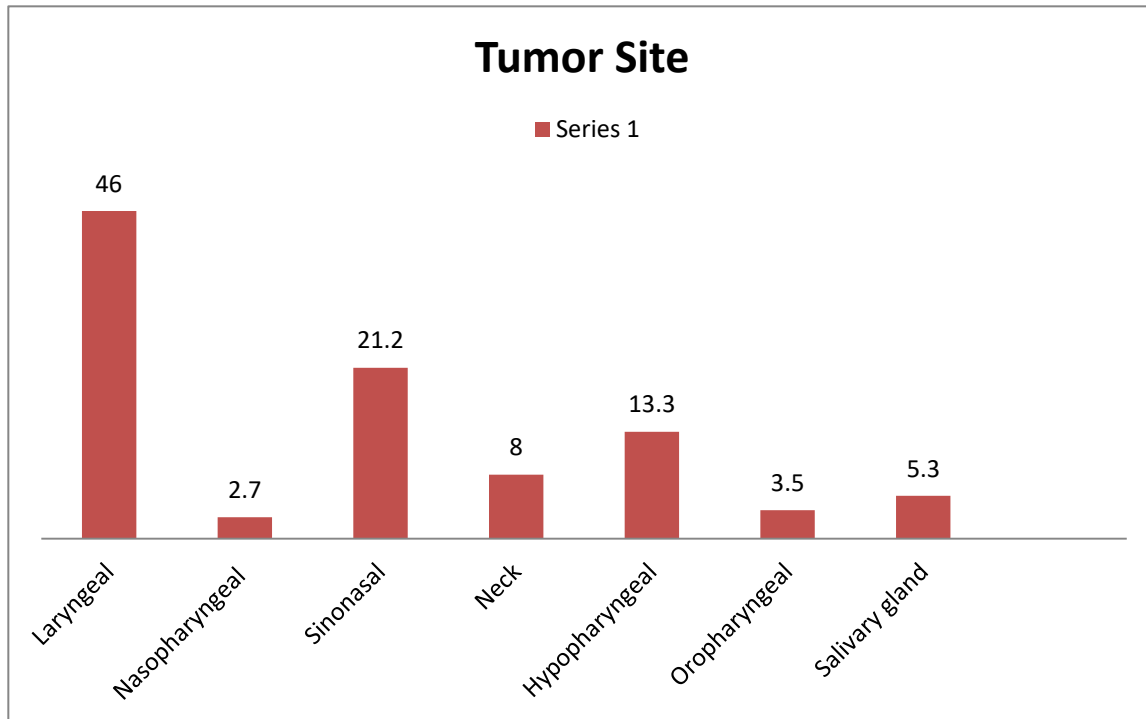


Figure 1: Tumor site distribution

3.3 Tumor Stage Distribution

Advanced stages (III and IV) composed majority of the patients in the study i.e.85.6%, with stage IV involving more than half of participants (52.2%).Stage I disease only involved 1.8% of participants.

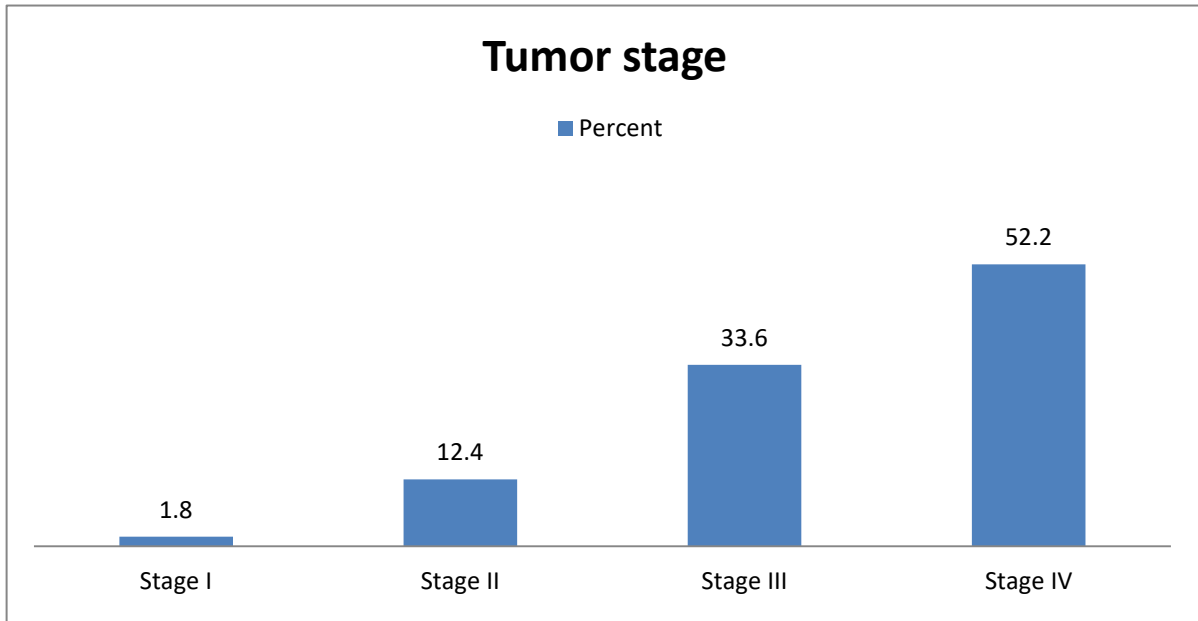


Figure 2: Tumor stage

3.4 DST Score

About 17% of patients presented to MNH with a pre-existing dietary risk while a good proportion of patients presented with no nutritional risk based on their diet (51%)

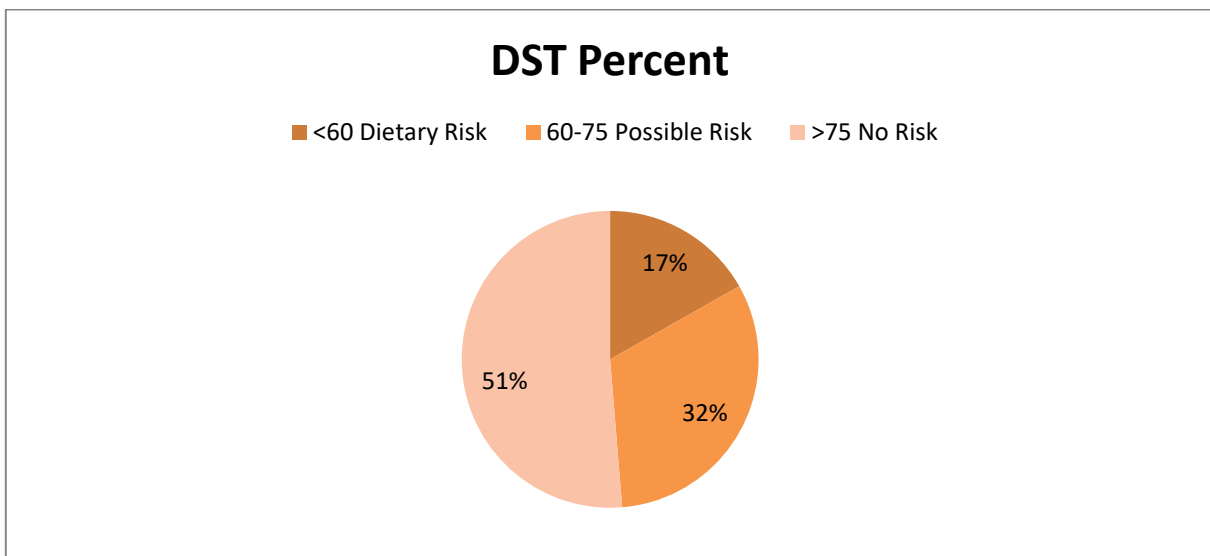
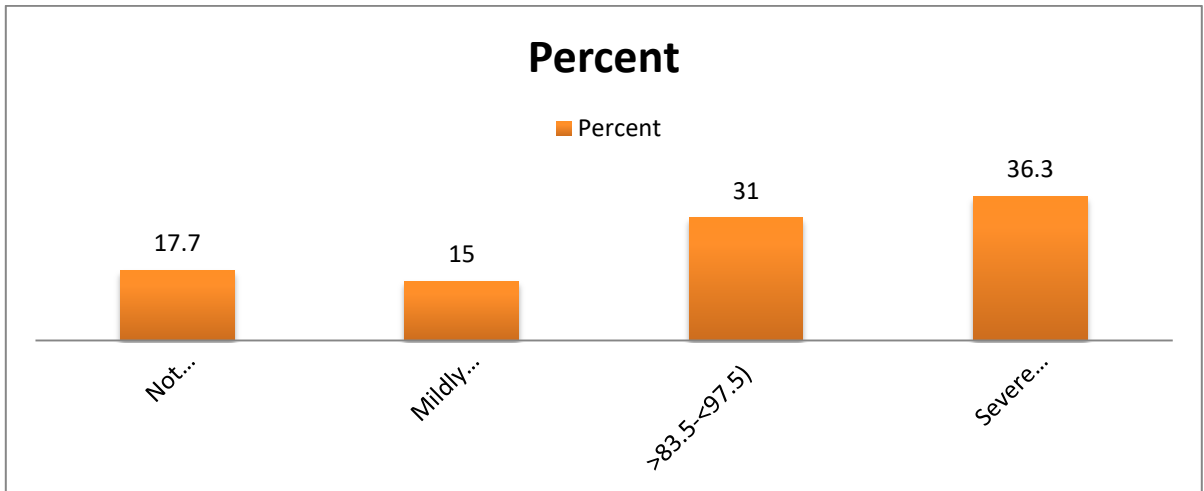


Figure 3: DST score

3.5 NRI Score

In this study it was found that 36.3% of patients presented with severe malnourishment as they scored less than 83.5 points based on NRI ratings, moderately malnourished patients made 31% of participants. Well-nourished patients were about 17.7%



3.6 BMI Score

Based on BMI scale 38% of participants were underweight (BMI score of equal or less than 18.4 points). In this scale it was noted that 1% of patients had obesity

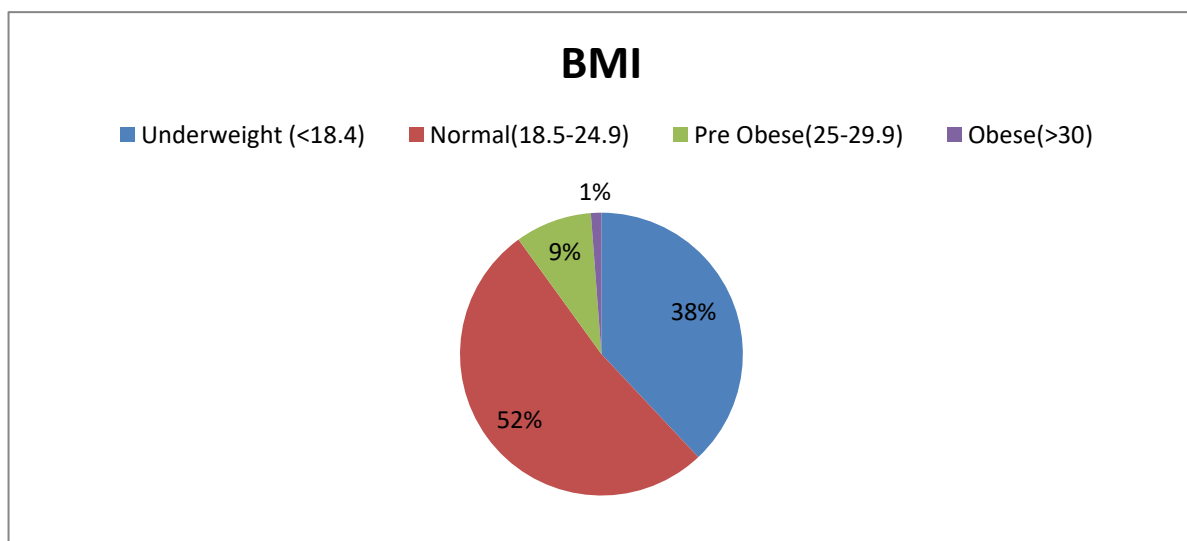


Figure 4: BMI score

3.7 Age/Sex and Tumor site

Laryngeal tumors were more common than any other HNC in Elderly and Middle age groups with 65.4% and 44.1% respectively, however this difference was not significant ($\chi^2=20.5$ $P=.058$). This study also found that laryngeal tumor was commonest tumor in men than all other HNC and the difference was significant ($\chi^2=27.67$ $P=.000$). In female hypopharyngeal tumor was much more common than the rest of the HN tumors with the same level of significance (23.1%).

Table 2: Age/Sex and Tumor site

	Laryngeal	Nasopharyngeal	Sinusal	Neck	Hypopharyngeal	Oropharyngeal	Salivary gland	Total
A:Age group								
15-47	14(35)	2(5)	14(35)	5(12.5)	3(7.5)	1(2.5)	1(2.5)	40(35.4)
48-63	21(44.7)	1(2.1)	7(14.9)	3(6.4)	7(14.9)	3(6.4)	5(10.6)	47(41.6)
=/>64	17(65.4)	0(0)	3(11.5)	1(3.8)	5(19.2)	0(0)	0(0)	26(23)
B:Sex Distribution								
Male	44(59.5)	3(4.1)	16(21.6)	3(4.1)	6(8.1)	1(1.4)	1(1.4)	74(65.5)
Female	8(20.5)	0(0.0)	8(20.5)	6(15.4)	9(23.1)	3(7.7)	5(12.8)	39 (34.5)
Total	52(46)	3(2.7)	24(21.2)	9(8)	15(13.3)	4(3.5)	6(5.3)	113(100)

3.8 Age/Sex and Tumor stage

Elderly patients presented late to healthcare with 88.4% of them presenting with stage III and IV disease though the difference was not significant ($\chi^2=3.34$ $P=.765$). Among male patients majority presented at an advanced disease stage (86.5%) $\chi^2=1.716$ $P=.633$

Table 3: Age/Sex and Tumor stage

	I	II	III	IV	Total
Age groups					
	n(%)				
15-47 Young adults	1(2.5)	7(17.5)	14(35)	18(45)	40(35.4)
48-63 Middle Aged	1(2.1)	4(8.5)	17(36.2)	25(53.2)	47(41.6)
=/ >64 Elderly	0(0)	3(11.5)	7(26.9)	16(61.5)	26(23)
Sex Distribution					
Male	2(2.7)	8(10.8)	24(32.4)	40(54.1)	74(65.5)
Female	0(0)	6(15.4)	14(35.9)	19(48.7)	39(34.5)

3.9 Tumor site/stage and Nutritional Status

Highest percentage of malnutrition was found in Oropharyngeal tumor (75%), followed closely by Hypopharyngeal and Nasopharyngeal tumor each with 66.7%. The difference was however not significant ($\chi^2 = 27.577$ P=.069). Stage IV patients were severely malnourished in greatest percentages and this finding was significant (57.6%) $\chi^2 = 64.414$ P=.000

Table 4: Tumor site/stage and Nutritional status

	Not malnourished(>100)	Mild malnourished(=/>97.5-100)	Moderately malnourished(=/>83.5-<97.5)	Severe malnourished<83.5	Total
A:Tumor site					
Laryngeal	13(25)	10(19.2)	14(26.9)	15(28.8)	52(46)
Nasopharyngeal	1(33)	0(0)	0(0)	2(66.7)	3(2.7)
Sinonasal	4(16.7)	6(25)	10(41.7)	4(16.7)	24(21.2)
Neck	1(14.3)	0(0)	3(42.9)	5(55.6)	7(6.2)
Hypopharyngeal	0(0)	0(0)	5(33.3)	10(66.7)	15(13.3)
Oropharyngeal	0(0)	1(25)	0(0)	3(75)	4(3.5)
Salivarygland	1(16.7)	0(0)	3(50)	2(33.3)	6(5.3)
B:Tumor Stage					
I	1(50)	0(0)	1(50)	0(0)	2(1.8)
II	11(78.6)	0(0)	1(7.1)	2(14.3)	14(12.4)
III	6(15.8)	10(26.3)	17(44.7)	5(13.2)	38(33.6)
IV	2(3.4)	7(11.9)	16(27.1)	34(57.6)	59(52.2)
Total	20(17.7)	17(15)	35(31)	41(36.3)	113(100)

3.10 DST score and NRI score

Patients with highest dietary risk had highest proportion of severe malnourishment at presentation (52.6) $\chi^2=10.879$ P=0.092

Table 5: DST score and NRI score

	Not malnourished (>100)	Mild malnourished(=/ 97.5-100)	Moderately malnourished(= />83.5-<97.5)	Severe malnourishe d<83.5	Total
DST score					
<60	1(5.3)	1(5.3)	7(36.8)	10(52.6)	19(16.8)
60-75	8(22.2)	6(16.7)	6(16.7)	16(44.4)	36(31.9)
>75	11(19)	10(17.2)	22(37.9)	15(25.9)	58(51.3)
Total	20(17.7)	17(15)	35(31)	41(36.3)	113(100)

CHAPTER THREE

4.0 DISCUSSION

4.1 Age and Sex Characteristics

This study found that majority of Head and Neck cancers were in patients aged 48-63 years, classified as middle aged, with a mean of 51.8 years, this finding is close to that by Righini(6) who found mean age in head neck cancer patients to be 59 years. Amaral (9) study found a similar pattern of head and neck cancer patients with a mean age of 57.1 years. A local study done at ORCI by Nundu found a similar age distribution for head and neck cancer with a mean age of 51 years(3). Sex distribution of participants showed male predominance with 65.5%. This finding is in congruence with the study by Nundu in ORCI in which 58.7% of HNC patients were male.

4.2 Nutritional status of HNC patients at presentation

Finding from this study revealed that 36.3% of patients presented at first time with severe malnourishment this was according to NRI score (<83.5 points). Again based on BMI score 38.1% of HNC presented at ENT department with underweight. However it should be noted that some patients had pre-existing nutritional risk based on their dietary intake which was assessed using Dietary Screening Tool by as originally pioneered by Bailey(17). According to DST categorization this study found that 16.8% of patients had prior nutritional risk which could explain the high proportion of malnutrition at presentation. Critical Weight Loss(CWL) is a common phenomenon in HNC, defined as involuntary weight loss of $\geq 5\%$ in one month, or $\geq 10\%$ in six months which is present in around (30-55%) of HNC patients(18). CWL phenomenon can explain the presentation of severe malnourishment at high rate in this study. A study by Jager (18) found that 19% of patients with HNC had CWL at presentation which is slightly lower rate compared to our study.

The difference with our scenario could be explained by late presentation as majority of patients had advanced stage (II&IV) i.e. 88.6%(see Figure 4). Another study by Kubrak found a contrasting evidence among patients with HNC in which only 5.1% of their patients presented with BMI of <18.5.

4.3 Anatomical site and nutritional status

It was found in this study that Oropharyngeal tumor patients presented with severe malnourishment at the highest rate of all HNC tumors assessed (75%) $\chi^2=30.079$ $P=.090$. This finding differed to the study of CWL by Jager(18) which showed the highest proportion of weight loss in patients with HNC was seen in Hypopharyngeal tumor(43%). This difference can be explained by the different tool used to assess nutrition, our study used NRI while Jager study used CWL. A study in Japan by Takenaka (11) had findings which were similar to the study by Jager showing highest proportion of malnutrition in head and neck cancer linked to hypopharyngeal tumors however this finding was not statistically significant. Oropharyngeal cancer is incriminated in severe malnutrition due to two mechanisms. Systemic effect occurs due to involvement of CNS by the regulation of satiety and sense of taste by an action of cytokines produced by host monocytes and tumor cells(19). Local effects of oropharyngeal tumor may impinge food intake and predispose patient to severe malnourishment these effects include odynophagia and dysphagia.

Another unique finding was that Nasopharyngeal tumor had higher rate of malnutrition compared to laryngeal tumor (66.7% vs 28.8 respectively, see table 4) . This finding is explained by the fact that majority of Nasopharyngeal tumor patients presented with relative higher proportion of an advanced disease(66.7% vs 44.2% had stage IV disease, $\chi^2=16.39$, $P=.565$) which contributed to their poor nutritional state at presentation.

Contrasting finding was found in a study by Jager-Wittenaar,2011(20) who found overall malnutrition to be 16% however his study was limited to cancer in the oral cavity and oropharynx which may explain lower incidence as compared to this MNH study.

4.4 Tumor stage and nutritional status

It was found in this study that severely malnourishment was present in stage IV patients for about (57.6%) $\chi^2 = 64.414$ $P = .000$. Advanced stage of the tumor is associated with large size of tumor which has mechanical effect of obstructing the food passage e.g. Oropharyngeal and Hypopharyngeal tumor. Another feature of advanced stage disease is involvement of multiple anatomical site e.g. advanced sinonasal tumor may present with an oral involvement by palatal extension which may end up causing dysphagia. This finding was in agreement with the study by Takenaka (11) which found advanced tumor staging in HNC had significant association with severe malnourishment (56%).

4.5 Pre-existing nutritional risk in patients with HNC

In our study it was noted that 16.8% of patients with HNC had nutritional risk which could have predispose them to malnutrition regardless of disease (Figure 5). These findings were comparable to the study by Esfahani (21) in Iran who studied the nutritional risk in Inoperable gastric adenocarcinoma, however in his study he found 87% of patients had moderate to severe nutritional risk. This large discrepancy might be explained by the cancer type in their study they included gastric tumor which directly affect the food uptake. On the contrary our study assessed multiple upper aerodigestive tumors which some are not directly involved with dietary intake like sinonasal tumors. Again the study by Esfahani used a different methodological approach by employing Patient Generated Subjective Global Assessment (PG-SGA) tool and they clustered patient into moderate and severe malnutrition risk.

4.6 Tumor site

It was found in this study majority had laryngeal tumor which was followed by sinonasal and hypopharyngeal tumors with 46%, 21% and 13 respectively, our study differed from the study by Magnano (5) whom Oropharyngeal and Oral tumors predominated over Laryngeal and Hypopharyngeal tumor with 56.5% vs 46.5% respectively. The discrepancy might be explained by methodological difference in which Magnano study followed patients over 4 years span (2009-2013) while our study only covered the span of 6 months.

The similar pattern of HNC was found in Righini study in which Oropharyngeal tumors were high on the list, this study also had a similar methodological approach to our study i.e. they used NRI and BMI as nutritional criteria but they added an extra criteria of Weight Loss(WL) of more than/less than 10% to categorize malnutrition.

The finding in our study corresponded to local study by Ashfaq(22) in ORCI who found that laryngeal tumor was high on the list with 19.7% of all HNC tumors. The lower percentage in his study is explained by lower sample size which was 66 compared to our study which involved 113 participants. Another local study by Nundu(23) which studied effect of chemo-radiotherapy in HNC also found laryngeal tumor as a leading pathology with 17.3%, the lower percentage in his study is explained by the source of patients who were not just from ENT department but also from OMFS and General surgery departments which consisted other tumors like oral cavity tumors, facial, maxillary and mandibular tumors.

4.7 Tumor Stage

Our study found that 85.6% of patients presented with advanced disease i.e. Stage III and IV, stage IV alone involving more than half of participants (52.2%). The finding in our study differed from an Italian study(5) which found a slightly lower proportion of advanced disease. Righini(6) in France had a findings corresponding to Mognano but his study categorized patients in two groups based on weight loss of $\geq 10\%$. Those who were less malnourished ($WL < 10\%$) advanced disease was found in 35% and those who were severely malnourished had 60% of patients with an advanced disease. The differences seen in these studies are explained by geographical differences as the two studies were done in Europe and it's documented that cancers in Africa are diagnosed at an advanced stage and with relatively higher level of malnutrition(12).

4.8 BMI findings

Based on this scale it was noted that 38% of patients had underweight at presentation. It also revealed that 1% had obesity. The finding of obesity in these patients is supported by literature which shows that obesity alone is an independent risk factor for about 20% of all cancer(24).

In head and neck region obesity has been linked to Thyroid tumor and Non Hodgkin lymphomas. Mechanism for this relationship is the presence of low grade inflammation(esp.IL-6 cytokine) in obese people which promotes malignant cell growth and progression(24). These findings were contrary to those by Kaduka(12) in Kenya who found malnutrition at presentation was present in only 13.4% of participants, with male dominance. The difference is explained by, the later study which involved tumor other than HNC such as Digestive system tumors, breast, hematopietic e.t.c

4.9 Age/Sex and tumor site

It was found in this study that among middle aged and the elderly laryngeal tumor was commonest pathology with 44.1% and 65.4% respectively. This finding concurred with most of literature in HNC which tumors commence from 6th to 7th decades. The finding that most laryngeal tumors occur in males cannot be overemphasized as most literature links it to use of alcohol and smoking which have synergistic effect of carcinogenesis and the two risk factors are so common in men. Ellis(25) in United Kingdom he did 15 year review of national cancer data and found >80% occurred in men.

4.10 Age/Sex and tumor stage

It was evidenced in our study that 88.4% of elderly patients were presenting with stage III and IV disease though the difference was not significant. This finding is explained by the fact that majority of HNC patients who show up in health facilities are aged \geq 50yrs(11)and they present with an advanced disease(12)

4.11 Tumor site/stage and Nutritional Status

This study evidenced an alarming rate of malnutrition in HNC. The highest proportion of malnutrition was found in Oropharyngeal tumor, followed by Hypopharyngeal and Nasopharyngeal tumor each with 66.7%.These high rates are supported by a whole body of evidence, Kaduka (12)in Kenya found prevalence of malnutrition in HNC was 17.6% in lip oral cavity and pharyngeal tumor combined, however in their study they used BMI as a sole

criteria for nutritional assessment which some authors incriminates it for its poor sensitivity in overweight and obese patients(5). Nundu in ORCI found that majority of patients with hypopharyngeal cancer had malnutrition 85.7% followed by Oropharyngeal cancer 60%,however in his study he just used BMI as Nutritional assessment tool and he assessed nutrition after the use of radiotherapy.

4.12 DST score and NRI score

Our study found that patients with highest dietary risk had highest proportion of severe malnourishment at presentation (52.6%) $\chi^2=10.879$ $P=0.092$.Its evidenced that malnutrition is a common feature associated with, and which predisposes patients with HNC to poor prognostic outcomes(11).

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATION

5.1 Conclusion

Laryngeal tumor has been shown to be more common in men and it is so much related to advanced age.

Most of patients with HNC had severe malnourishment at presentation with

Oropharyngeal tumor having the highest rate of severe malnourishment compared to other anatomical sites in Head and Neck. Hypopharyngeal and nasopharyngeal tumors was second and third respectively and most participants had pre-existing nutritional risk regardless of their disease state.

Advanced disease stage is significantly associated with severe malnutrition.

Elderly men have a tendency to present to health facilities with an advanced disease.

Poor nutrition prior to disease predisposes HNC patients to severe malnourishment during illness. The proportion of malnourishment is higher in these patients than patient who had normal nutritional status prior to illness

5.2 Recommendations

There should be a paradigm shift towards health seeking behavior in Tanzanian community. The later should be educated more on avoidance of risky practices related to cancer etiology.

Health care practitioners should address patients with HNC with care by providing adequate nutritional support as required.

Physicians should create habit of assessing nutritional status in HNC patients, while taking care of them as its well documented that poor nutrition has effect on success of chemoradiotherapy and prognosis in general. Knowledge of nutrition status by clinicians will enable corrective measure to be instituted timely and improve success of therapy.

The public should have a tendency to good dietary behaviors as this practice has impact on disease state. Again literature links good diet to promotion of immunity against various pathologies including HNC.

Public health campaigns should heighten the awareness of laryngeal tumors among men in Tanzania and the associated risk factors such as Cigarette smoking and excessive alcohol use should be addressed to the public that they shun away from risky behaviors.

There's a role of educating the public against late attendance to health facilities when the disease is advanced and little can be done to help.

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APPENDICES

Appendix I: Dietary screening tool (DST) Bailey-English Version

Scoring components, questions, and point classifications of the dietary screening tool (DST)

DST component Point classification

Whole fruit and juice 15

How often do you usually eat fruit as a snack? (5)

How often do you eat fruit (not including juice)? (5)

How often do you drink some kind of juice at breakfast? (5)

Vegetables 15

How often do you eat carrots, sweet potatoes, broccoli, or spinach? (8)

How many different vegetable servings do you usually have at your main meal of the day? (7)

Total and whole grains 15

How often do you usually eat whole-grain breads? (5)

How often do you usually eat whole-grain cereals? (5)

How often do you eat hot or cold breakfast cereal? (5)

Lean proteins 10

How often do you eat chicken or turkey? (5)

How often do you eat fish or seafood that is not fried? (5)

Added fats, sugars, and sweets 25

How often do you usually eat candy or chocolate? (4)

How often do you eat crackers, pretzels, chips, or popcorn? (4)

How often do you eat cakes or pies? (4)

How often do you eat cookies? (4)

How often do you eat ice cream? (4)

Do you usually add butter or margarine to foods such as bread, rolls, or biscuits? (1)

Do you usually add fat (butter, margarine or oil) to potatoes and other vegetables? (1)

Do you use gravy (when available) at meals? (1)

Do you usually add sugar or honey to sweeten your coffee or tea? (1)

Do you usually drink wine, beer, or other alcoholic beverages? (1)

Dairy 10

How often do you drink a glass of milk? (5)

How many servings of milk, cheese, or yogurt do you usually have each day? (5)

Processed meats 10

How often do you eat cold cuts, hot dogs, lunchmeats, or deli meats? (5)

How often do you eat bacon or sausage? (5)

Total 100

Dietary supplement use +5

1 The scores in parentheses represent the specific points assigned to each question within the major diet component

Categories.

Appendix 2: DST (Swahili version)

1 Matunda na Sharubati(juisi)	Kila wakati kwenye mlo mkuu	Angala u mara moja kwa siku	Mar a 3-4 kwa wiki	Mara 1 kwa wiki	Chini ya mara moja kwa wiki	Jumla(5)
Mara ngapi unakula matunda kama mlo						5
Mara ngapi unakula matunda						5
Mara ngapi unakunywa juisi kwenye						5
2 Mboga za majani						
Mara ngapi unakula karoti,viazi vitamu,brokoli au spinachi						8
Unakula mboga za majani kwa kiasi gani(wingi) kati mlo wako wa siku						7
3 Vyakula vya nafaka						
Mara ngapi unakula mkate						5
Mara ngapi unakula vyakula vingine vya wanga(Ugali,wali,uji)						5
Ni mara ngapi unakula chakula cha asubuhi chenye nafaka						5

4	Protini						
	Mara ngapi unakula kuku au nyama ya ng'ombe						5
	Mara ngapi unakula samaki au mazao ya bahari ambao hawajakaangwa						5
5	Mafuta na Sukari	Angala u mara moja kwa siku	Mara 3-6 kwa wiki	Mar a 1-2 kwa wiki	Mara 2-3 kwa mwezi	Mara moja kwa mwezi/si li kabisa	Alama
	Mara ngapi unakula pipi au chokleti						4
	Mara ngapi unakula chipsi au popcorn						4
	Mara ngapi unakula keki						4
	Mara ngapi unakula biskuti						4
	Mara ngapi unakula ice cream						4
	Je ni mara ngapi unakula mkate ukiwa na siagi au butter						1
	Je unaongeza Mafuta(siagi,butter)kwenye viazi au mbogamboga zingine						1
	Je unatumia supu ya nyama (ikiwepo)						1
	Je unatumia asali au sukari						1

	kwenye chai au kahawa						
	Je unatumia mvinyo,bia au aina yoyote ya kilevi						1
6	Mazao ya maziwa	Kila wakati kwenye mlo mkuu	Angala u mara moja kwa siku	Mar a 3-4 kwa wiki	Mara 1 kwa wiki	Chini ya mara moja kwa wiki	Jumla(5)
	Mara ngapi unakunywa glasi ya maziwa						5
	Mara ngapi unakula jibini au mtindi						5
7	Mazao ya nyama						
	Ni mara ngapi unakula nyama,au nyama ya kopo						5
	Ni mara ngapi unakula soseji						5
	Jumla						100

Appendix 4: Consent Form – English Version

DIRECTORATE OF RESEARCH AND PUBLICATIONS

Reg No. **Date**.....

Consent to participate in a research study

Greetings. I am Dr. Peter Nyakubega, a postgraduate student, pursuing a Master's degree in Medicine (MMed Otorhinolaryngology) at Muhimbili University of Health and Allied Sciences. I am conducting a research on NUTRITIONAL ADEQUACY AMONG HEAD AND NECK CANCER PATIENTS AT MNH

Purpose of the study

To determine nutritional adequacy among patients with Head and Neck cancer attending ENT services at MNH.

Participants of the study

All head and neck cancer patients attended at Muhimbili National Hospital ENT department during the study period.

Participants will undergo a thorough history, head and neck examination, weighed and taken their height. Also blood sample will be taken to assess their Serum albumin level which will be used to assess their nutritional status. Participants will also be interviewed about their prior nutritional status using dietary screening tool. If you decide not to participate in this study, your care at ENT department will not be affected in any way possible

Confidentiality

All the participants who will be included in the study will be identified by their numbers and thus their names will not appear. The information obtained will be kept under a strict locked environment where it is only the researcher will have access and will be destroyed after the dissertation has been submitted and accepted for the award of a postgraduate degree.

Risk

No harm is expected to occur upon your participation in this study.

Benefits

If you consent to participate in this study, you will benefit from understanding your nutritional status, plan on treatment and prevention of future complications. The results of the study will also help bridge the gap of knowledge and bring awareness among otorhinolaryngologists, nutritionists, public health specialists and policymakers on the status of malnutrition in head and neck cancer

Right to withdrawal

Participating in this study is completely your choice. You can withdraw at any particular moment regardless of signing the consent form. You can even refuse to respond to any question in the questionnaire.

Whom to Contact

In case of any concern or question about the study, you can contact the researchers, Dr Peter Nyakubega (P.O BOX 7195 Dar es Salaam, Tel 0717463759), Dr Enica Richard (MUHAS, P.O. BOX 65001 Dar es Salaam, Tel +255754307717). You may also contact the Chairperson of the Senate, Research and Publications Committee, Dr. Bruno Sunguya P.O.BOX 65001, Dar es Salaam, for any matters concerning ethical violation of the study.

Declaration

Ihave read the contents in this form. My questions have been answered and I agree to participate in this study

Signature of participant.....

Signature of researcher/research assistant.....

Appendix 5: Consent Form (Swahili Version)**CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI****KURUGENZI YA TAFITI NA UCHAPISHAJI****IDHINI YA KUSHIRIKI KWENYE UTAFITI**

Namba ya usajili.....

Tarehe.....

Habari,

Mimi naitwa Dr Peter Nyakubega, ni mwanafunzi wa shahada ya Uzamili ya udaktari bingwa wa, masikio, pua na koo, katika chuo kikuu cha Afya na sayansi shirikishi Muhimbili. Nafanya utafiti kuangalia ukubwa wa tatizo, lishe duni kwa wagonjwa wa saratani za eneo la kichwa na shingo kwa wagonjwa wanaotibiwa katika hospitali ya taifa Muhimbili,

Usiri

Washiriki wote wa utafiti huu hawatatambuliwa kwa majina yao ila kwa namba. Habari zote za washiriki zitahifadhiwa/zitafungiwa mahali salama ambapo mtafiti mkuu tu ndiye atakayekuwa na funguo na makabrasha yote yatateketezwa mara baada ya utafiti kuisha

Lengo la utafiti

Kuangalia utoshelevu wa lishe kwa wagonjwa wenye saratani za eneo la kichwa na shingo wanaotibiwa katika idara ya masikio pua na koo katika hospitali ya taifa ya Muhimbili

Washiriki wa utafiti

Washiriki kwenye utafiti huu ni wagonjwa wote wenye tatizo la saratani ya kichwa na shingo waliotibiwa katika idara ya masikio pua na koo katika hospitali ya taifa Muhimbilikwa kipindi cha utafiti.

Washiriki wote watasikilizwa matatizo yao, watafanyiwa uchunguzi ikiwemo kufanyiwa kipimo cha uzito urefu na kipimo cha damu (Serum albumin) ambacho ni kiashiria cha hali ya lishe. Pia washiriki wataulizwa kuhusu hali ya lishe kabla ya ugonjwa kwa kutumia dodoso la lishe. Ukiamua kutoshiriki utafiti huu huduma yako katika idara ya pua koo na masikio haitaathirika kwa namna yoyote.

Usiri

Washiriki wote wa utafiti huu hawatatambuliwa kwa majina yao ila kwa namba. Habari zote za washiriki zitahifadhiwa/zitafungiwa mahali salama ambapo mtafiti mkuu tu ndiye atakayekuwa na funguo na makabrasha yote yatateketezwa mara baada ya utafiti kuisha

Madhara

Hakuna madhara yanayotarajiwa kwa washiriki wa utafiti.

Faida

Ushiriki wako katika tafiti huu utakusaidia kutambua ugonjwa wako, matibabu, athari na pia njia mbali mbali ya kuzuia athari zaidi. Matokeo ya utafiti huu yatasaidia kuongeza ufahamu kwa wahudumu wa afya na watunga sera juu ya uwezekano wa kuathirika kwa hali ya lishe baada ya kupata saratani ya eneo la kichwa na shingo, na hivyo kuongeza ufahamu katika kada mbalimbali kama madaktari bingwa wa, upasuaji wa maskio, pua na koo, wataalamu wa lishe pamoja na wataalanu wa afya ya jamii katika kumhudumia mgonjwa wa saratani ya kichwa.

Haki ya kujitoa

Ushiriki katika utafiti ni wa hiyari, na mshiriki yoyote ana haki ya kuamua kujiondoa katika utafiti wakati wowote. Kujiondoa hakutaathiri huduma unayopaswa kupewa.

Mawasiliano

Ikiwa kuna swali lolote kuhusu utafiti huu, tafadhali wasiliana na Dkt Peter Nyakubega (SLP 7195 Dar es salaam, Simu +255717463759), Dr Enica Richard (SLP 65001 Dar es salaam, Simu +255754307717) Chuo kikuu Cha Afya na Sayansi Shirikishi Muhimbili S.L.P 65001 Dar es Salaam. Hata hivyo, ikiwa kuna suala lolote linalohusu mwenendo wa kimaadili ya utafiti wa kimatibabu, wasiliana na Mwenyekiti wa Kamati ya Tafiti na Machapisho wa Chuo Kikuu cha Afya na Sayansi shirikishi Muhimbili, Dkt. Bruno Sunguya, S.L.P 65001, Dar es salaam.

Sahihi ya mshiriki.....

Sahihi ya mtafiti/mtafiti msaidizi.....

Appendix 6: Assent Form-English Version**ASSENT FORM FOR CHILDREN FROM 7 YEARS TO 17 YEARS****DIRECTORATE OF RESEARCH AND PUBLICATIONS, MUHAS****Assent form to participate in a research study on nutritional status among head and neck cancer patients at Muhimbili National Hospital**

My name is Dr. Peter Nyakubega, a postgraduate student at MUHAS; I am inviting you to participate in a research study about nutritional status among head and neck cancer patients at Muhimbili National Hospital

Your parent knows about this study, and gave permission for you to be involved. If you agree, I will ask you questions concerning your disease and measure your weight, height and then I will take a blood test for further investigations, If you decide not to participate in this study, your care services will not be affected. Benefits of this study include awareness of how nutritional status affects Head and Neck Cancer among your parents and hospital staffs in general that will help proper future management of malnutrition in head and neck cancer patients.

I don't expect that any big problems will happen to you as part of this study, but you might feel sad or minor discomfort when we ask about things that happen during the course of your illness, taking your weight, height and while taking a blood test.

No one will be mad at you if you decide not to proceed with this study. Even if you start the study, you may ask questions about the study at any time.

If you decide to be in the study I will not tell anyone else how you respond or act as part of the study. Even if your parents or teachers ask, I will not tell them about what you say or do in the study.

Signing here means that you have read this form and understand it correctly and that you are willing to be in this study

Participant

Name.....Signature.....

Name of parent/guardian.....Signature.....

Name of researcher/research assistant.....Signature.....

Date:.....

Appendix 7: Assent Form – Swahili Version

FOMU YA KUTOA IDHINI YA KUSHIRIKI UTAFITI KWA WATOTO WA UMRI WA MIAKA 7-17

KURUGENZI YA UTAFITI NA UCHAPISHAJI, MUHAS

Fomu ya kutoa idhini kushiriki kwenye utafiti wa hali ya lishe kwa wagonjwa wa saratani ya kichwa na shingo katika hospitali ya Taifa Muhimbili.

Naitwa Dk Peter Nyakubega, mwanafunzi wa shahada ya uzamili chuo kikuu cha Afya na Sayansi Shirikishi Muhimbili, Ninakualika kushiriki kwenye utafiti unaohusiana na hali ya lishe katika wagonjwa wa saratani ya kichwa na shingo katika Hospitali ya Taifa Muhimbili.

Mzazi wako anajua kuhusu huu utafiti na amekuruhusu ushiriki. Kama utakubali nitakuuliza maswali yanayohusiana na ugonjwa wako, nitakupima uzito na urefu wako, kisha nitachukua kipimo cha damu kwa ajili ya uchunguzi zaidi. Kama utaamua kutoshiriki, huduma zako hapa hospitali hazitaathirika. Manufaa yatakayopatikana kutokana na utafiti huu ni ufahamu juu ya hali ya lishe inavyoathiri ugonjwa wa saratani ya Kichwa na Shingo utaongezeka kwa wazazi wako na wafanyakazi wa hospitali, hivyo kuboresha tiba kwa wagonjwa wa saratani ya Kichwa na shingo wenye lishe duni.

Sitarajii kwamba utapata madhara makubwa kutokana na ushiriki wako kwenye huu utafiti, lakini unaweza kujisikia huzuni au usumbufu tutakapo kuuliza kuhusu mambo yaliyokupata wakati wa ugonjwa wako, kupima uzito, urefu na wakati wa kipimo cha damu.

Hakuna atakayekukasirikia kama utaamua kutokuendelea na utafiti huu. Hata utakapoanza kushiriki unaweza kuuliza maswali kuhusu utafiti huu muda wowote.

Kama ukiamua kushiriki huu utafiti sitamwambia mtu yoyote kuhusu ulivyojibu au ulivyofanya katika utafiti. Hata ikitokea wazazi wako au waalimu wakiuliza, sitawaambia ulichojibu au ulichofanya kwenye utafiti.

Kuweka sahihi hapa inamaanisha umesoma maelezo ya liyomo kwenye fomu hii na kuyaelewa kwa usahihi,na pia uko tayari kushiriki kwenye utafiti.

Jina la

Mshiriki.....Sahihi.....

Jina la mzazi/mlezi.....Sahihi.....

Jina la Mtafiti/Mtafiti msaidizi.....Sahihi.....