

ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH HEAD AND NECK
CANCER AT KENYATTA NATIONAL HOSPITAL

Principal author

Dr Marianne Gitau
H58/ 76386/ 2009
MBChB (UoN)
Department of ENT/Head and Neck Surgery
University of Nairobi

Supervisors

1. Dr Peter Mugwe
MBChB (UoN), MMED ENT Head and Neck Surgery (UoN)
Consultant ENT Surgeon, Senior Lecturer
Department of ENT/Head and Neck Surgery
University of Nairobi
2. Dr Musa Kippingor
MD (Carol Davilla. Buch), MMED ENT Head and Neck surgery (UoN)
Consultant ENT Surgeon
Department of ENT/Head and Neck Surgery
Kenyatta National Hospital

A dissertation submitted as partial fulfilment of the requirements by the University of Nairobi for the award of the degree of Masters in Medicine in ENT/ Head and Neck surgery.

DECLARATION

This is my original work which has not been presented for a degree award at any other university.

Signed _____ Date _____

Dr Marianne Gitau

This thesis will be supervised by:

Signed _____ Date _____

Dr Peter Mugwe
Consultant ENT Surgeon, Senior Lecturer
Department of ENT/Head and Neck Surgery
University of Nairobi

Signed _____ Date _____

Dr Musa Kippingor
Consultant ENT Surgeon
Department of ENT/Head and Neck Surgery
Kenyatta National Hospital

DEDICATION

I dedicate this book to my family who walked with me through this journey, for their unwavering support and prayers. Thank you.

To Kenneth Mbira, who believed in me and cheered me on at every stage. Thank you.

I wish to thank all the patients who made this possible, for their patience, time and for making this study a success.

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1.0 ABSTRACT

ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH HEAD AND NECK CANCER AT KENYATTA NATIONAL HOSPITAL

Main objective: To determine the quality of life in head and neck cancer patients at Kenyatta National Hospital using the European Organisation for the Research into Treatment of Cancer (EORTC) Quality of life core questionnaire 30(QLQ C30) and QLQ Head and neck module 35(H&N 35) questionnaire.

Specific objectives: To assess the reliability and validity of the QLQ C30 and QLQ H&N 35 questionnaires; to determine whether age, gender, localisation, stage and prior treatment modality have an impact on the quality of life.

Study Design: Descriptive cross sectional study.

Materials and methods: The quality of life (QOL) of patients suffering head and neck cancer was assessed using the EORTC QLQ C30 and QLQ H&N 35 questionnaires.

123 patients who presented to the Radiotherapy department after a diagnosis of head and neck cancer filled in the questionnaires.

Results: The QLQ C30 and the QLQ H&N 35 demonstrated acceptable reliability/internal consistency. They also displayed sufficient criterion validity and were sensitive to group differences with regard to age, gender, tumour stage, tumour site and prior treatment.

Conclusion: The results obtained support the use of the two questionnaires in the assessment of quality of life in head and neck cancer patients. There is a negative co-relation between tumour stage and QOL. Advancing age and co-morbidity influence QOL.

2.0 ACRONYMS AND ABBREVIATIONS

BFI:	Brief fatigue Inventory
BPI:	Brief pain inventory
EORTC:	European Organisation for Research into the Treatment of Cancer
FACT –G:	Functional Assessment of Cancer Therapy-General
GHS:	Global Health Status
H&N 35:	Head and Neck 35 questionnaire
HNC:	Head and Neck cancer
HRQOL:	Health related quality of life
KNH:	Kenyatta National Hospital
MOS SF-36:	The Medical Outcomes Study-Short Form-36
POMS:	The Profile of Mood States-Fatigue Scale
QLQ:	Quality of life questionnaire
QOL:	Quality of life
SIP:	Sickness Impact profile
UWQOL:	The University Washington QOL Questionnaire
VHNSS:	The Vanderbilt Head and Neck Symptom Scale
WHO:	World Health organisation

3.0 BACKGROUND ON QUALITY OF LIFE

Head and Neck Cancers (HNC) refer to primary tumours arising from the larynx, pharynx, oral cavity, paranasal sinuses and the salivary glands. These sites are structurally complex and serve the critical functions of speech, swallowing and respiration.

The presence of these tumours can result in gross deformities which lead to the loss of facial integrity which may have profound emotional and social effects on the patient. In this regard, HNC patients are unique with respect to the potential adverse effect of tumour and its treatment on their Quality of life (QOL).

It is therefore imperative for clinicians to understand the meaning of QOL, its measurement and its use. Quality of life can only be evaluated from a patient's perspective and it is determined by intrinsic patient characteristics namely their beliefs, expectations and experiences.^[1]

The World Health Organisation (WHO) defines Quality of Life (QOL) as “an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.”^[2]

Quality of Life is therefore a global construct that has developed in response to the perceived need to assess the patient's overall sense of wellbeing and how it relates to disease and disease treatment^[3-5].

Quality of life measures seek to obtain a comprehensive, multi-dimensional picture of the patient's “total health related experience” and by doing so, evaluate broad domains including emotional, physical, functional, social, financial and spiritual well-being^[5,6].

The relationship between symptoms and the domains of QOL is significant. A symptom is defined as a perceived alteration in sensation, and majority of QOL questionnaires incorporate questions that are based on symptomatology. It is therefore important to distinguish between symptom surveys and quality of life measures.

Possible relationships between quality of life and symptoms include:^[7]

1. Quality of life decreases in a linear manner as symptom intensity increases.
2. Quality of life may not be affected until symptoms become intense.
3. Low symptom intensity causes a marked decrease in QOL.

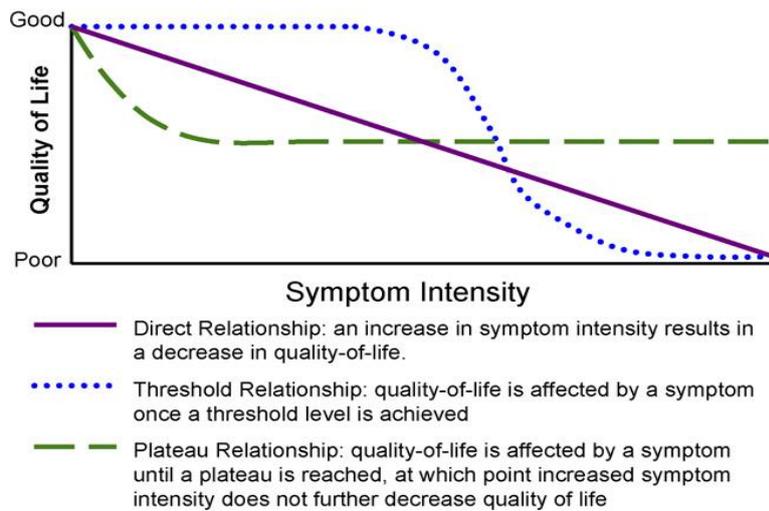


FIGURE 1: POTENTIAL RELATIONSHIP BETWEEN QOL AND SYMPTOMS

Possible temporal relationships between QOL and symptoms: [7]

1. The relationship may remain stable over time.
2. The patient may accommodate to a symptom thus the effect of a symptom on QOL may diminish over time.
3. The effect of a symptom may increase over time as the patient fatigues

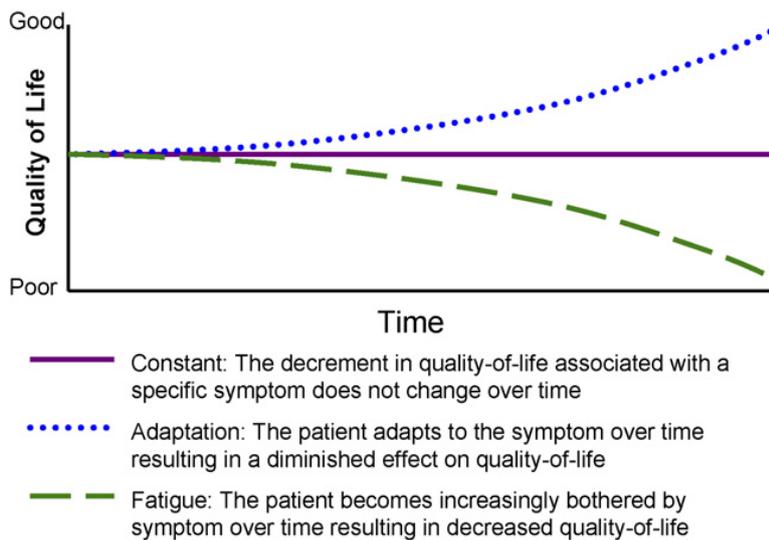


FIGURE 2: POTENTIAL RELATIONSHIP BETWEEN QOL AND SYMPTOM DURATION

Other than symptom burden, other variables that impact on QOL include biological/physical factors, function, the perception of general health, function and health related quality of life (HRQOL).^[8]

3.1 SIGNIFICANCE OF QOL IN HNC

Quality of life data can provide information that guides healthcare related decision making on several levels ^[9].

1. It can help shape public policy and health care decisions made by governmental and private institutions.
2. It can guide the research agenda of pharmaceutical companies and cooperative groups.
3. It can provide information to guide clinical decision making by physicians

Ideal QOL studies should provide information on the impact of specific treatments on patient outcomes. This information can then be disseminated to the patient and assist in decision making (with regard to their treatment options).

Communication between the patient and his/her physician can be improved as a result of the information obtained from QOL studies. Identification of potential problems that have a significant impact on QOL also becomes easier. Screening for these problems and prioritisation of their treatment may therefore improve their QOL.

3.2 LIMITATIONS OF QOL RESEARCH IN HNC

Accessibility of quality of life research tools to clinicians is limited and is not part of routine practice. ^[7] As a result many clinicians are not familiar with the available tools and more so how to score and interpret the results.

There is no gold standard with regard to which tool is the most effective, sensitive or reliable despite there being numerous QOL tools in existence.

3.3 HEAD AND NECK HEALTH RELATED QOL INSTRUMENTS

Health related quality of life (HRQOL) measurement tools should be easy to administer, easy to understand, and easy to score.

They should be clinically relevant, valid (measure what they say they measure), reliable (produce the same results in the same population) and sensitive (responsive to change in patient's condition). Their importance lies in assisting physicians in the detection of clinically significant changes in the patient's condition.

Currently, there are several HRQOL instruments which are being used to measure QOL in head and neck cancer patients. These instruments have been developed from research environments and fall into four major categories:

1. Disease specific
2. Generic
3. Symptom specific
4. Site or treatment specific

3.31 DISEASE-SPECIFIC HRQOL INSTRUMENTS

These include the Functional Assessment of Cancer Therapy-General (FACT-G) ^[10, 11] and the European Organization for Research into the Treatment of Cancer core questionnaire (EORTC QLQ-C30) ^[12].

The FACT-G (version 4) contains 27 items that comprise 4 multi-item subscales.

The 30-item EORTC QLQ-C30 looks into cancer specific aspects of HEQOL in nine subscales. Both the FACT-G and the EORTC QLQ-C30 include a number of items that assess symptoms as well as functional and psychosocial aspects.

The EORTC QLQ-C30 questionnaire incorporates extensive QOL issues relevant to a broad range of cancer patients ^[13-18]. It has been validated for many types of cancer including head and neck cancer. It contains five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea/vomiting), a global QOL scale, and six single items (dyspnoea, insomnia, appetite loss, constipation, diarrhoea, and financial difficulties). Version 3.0 contains two additional items on role functioning and one additional item on overall health. The EORTC QLQ-C30 version 3.0 is meant to be used in conjunction with a tumour specific module which in this study is the EORTC QLQ-H&N 35 questionnaire.

The psychometric properties of the FACT-G and the EORTC-QLQ-C30 have established reliability, validity and sensitivity to change in clinical status. ^[19]

3.32 GENERIC HRQOL INSTRUMENTS

The Medical Outcomes Study-Short Form-36 (MOS SF-36) ^[11] and the Sickness Impact Profile (SIP) ^[12, 13] are the two most commonly used questionnaires. The MOS SF-36 has 36 items with eight subscales. Normative data from healthy adults as well as individuals with a variety of illnesses are available using this tool.

The SIP is a 136-item instrument that provides information about 12 areas of function and comprises two domains namely physical and psychosocial. Like the MOS, there are normative data using the SIP for a wide range of chronic illnesses.

3.33 SYMPTOM SPECIFIC INSTRUMENTS

Fatigue and pain are amongst the most common symptoms related to HNC and its therapy. The Brief Pain Inventory (BPI) and the Brief Fatigue Inventory (BFI) are similar in content and response format ^[20-22].

Each of these instruments assesses the intensity of the symptom (pain or fatigue) and the degree to which these symptoms interfere with daily life. Function, social wellbeing and mood are also inclusive despite these being symptom scales.

The Profile of Mood States-Fatigue Scale (POMS) is an 11-item adjective checklist that assesses both fatigue and vigour ^[23].

3.34 SITE AND TREATMENT-SPECIFIC HRQOL INSTRUMENTS

The two commonly used tools are the head and neck subscales for the FACT HN^[24] and EORTC questionnaires^[15, 20]. They provide site specific information which gives a better understanding of the function and symptom issues critical to this select group of patients.

They can be used in conjunction with the core questionnaires and as such broadly reflect symptomatology, general well being and functionality. They can prove to be lengthy and tiresome for weak and sickly patients.

The FACT-HN is an 11-item subscale of HNC specific problems and it has demonstrated sensitivity to change in clinical status^[25].

The EORTC QLQ H&N 35 is a 35-item questionnaire that addresses HNC problems in seven subscales^[15, 26]. It has also demonstrated sensitivity to change in clinical status.

The EORTC QLQ H&N 35 is meant to be used hand in hand with the QLQ-C30 in head and neck cancer patients. As mentioned above, it contains seven subscales (pain, swelling, taste/smell, speech, social eating, social contacts, and sexuality).

It has ten (10) single items relating to problems with weight loss, weight gain, affectation of teeth, dry mouth, cough, opening the mouth wide, sticky saliva, use of nutritional supplements, feeding tubes and analgesics.

Items 1 to 30 are scored on four-point likert-type categorical scales (“not at all”, “a little”, “quite a bit”, and “very much”). Items 31 to 35 have a “no/yes” response format.

All scales and items of the EORTC QLQ-C30 and QLQ-H&N 35 range in score from 0 to 100. A high score for a functioning or global QOL scale represents a high level of functioning or global QOL, whereas a high score for a symptoms scale or item represents a high level of symptoms or problems.

The University Washington QOL Questionnaire (UWQOL) is a brief tool that combines general QOL and symptom/function assessment^[27, 28]. The aim of this measure is to discriminate between patients with high and low QOL. There are nine disease-specific items and three general items that address global QOL. It has demonstrated stability and internal consistency.

The UWQOL is brief and easy to administer. Items for this tool were generated by experts in otolaryngology and specifically focus on deficits in eating and speech that frequently occur in HNC undergoing treatment. This tool is scored by the clinician after patient interview.

Other relatively brief tools (≤ 20 items) that address HNC specific concerns include:

1. The quality of life questionnaire for advanced HNC^[29]
2. The head and neck radiotherapy questionnaire, a 22-item tool that captures specific responses to radiation and fatigue/psychosocial concerns^[30]

3. The 14-item quality of life radiation therapy head and neck module focuses on the specific effects on swallowing, speech and appearance^[31]
4. The Vanderbilt Head and Neck Symptom Scale (VHNSS)^[32, 33] a 27-item instrument that taps symptoms related to dietary intake, swallowing deficits, and psychosocial concerns.

As shown above, there are many QOL research instruments available, yet none of these has been declared the gold standard. The EORTC QLQ C-30 and the EORTC QLQ H&N 35 questionnaires will be used in this study to assess quality of life in Kenyan head and neck cancer patients.

4.0 LITERATURE REVIEW

The EORTC QLQ C-30 questionnaire has been used in various studies to assess its reliability and validity in different languages^[34-40]

A study by Vickery et al using 51 patients and 44 of their partners who filled in the Hospital Anxiety and Depression Scale, Psychosocial Adaptation to Illness Scale, Dyadic Adjustment Scale, and European Organisation for Research and Treatment of Cancer Quality Of Life Scale together with the Head and Neck Cancer module showed that partners reported greater distress than patients on some of the scales. On the EORTC the patients showed a lower QOL as compared to their partners.^[41]

Viklund et al used the EORTC QLQ C-30 together with an oesophageal module to assess QOL after oesophageal surgery and found it to be a reliable tool in assessment of quality of life.^[42]

Abendstein et al performed a 5 year prospective descriptive study on 357 patients from Norway and Sweden who had histologically verified carcinomas using the EORTC QLQ C-30 and QLQ H&N-35 questionnaires. It was a follow-up study. In the results, there was not much clinical difference in QOL between baseline and 5 years.^[43]

A 12 country study was performed on 622 head and neck cancer patients to test the reliability and validity of the EORTC QLQ C-30 and QLQ H&N 35 questionnaires. The questionnaire was well accepted by the patients and compliance was high. The QLQ-H&N35 was found to differentiate disease status, site and patients with different Karnofsky performance status as well as changes over time.^[15]

The QLQ C-30 version 3.0 was shown to be more reliable than previous versions. The two questionnaires were therefore found to be reliable, valid and applicable to broad multicultural samples of head and neck cancer^[15]

The EORTC QLQ H&N-35 was used in a cross sectional study using 116 of 120 recurrence free head and neck cancer patients. The psychometric properties of the EORTC H&N35 questionnaire were confirmed and it was found to detect correlations between clinical factors (performance status, gender, age, stage, site, time since therapy, treatment) and a large

number of QOL factors. “The EORTC H&N35 in conjunction with EORTC C-30 is a valid and informative tool in assessing quality of life in Danish head and neck cancer patients”. [44]

Bjordal et al performed a study to validate the EORTC QLQ C30 and H&N 35 questionnaires and concluded that these are valuable tools for assessing HRQOL in clinical studies of patients with head and neck cancer. [18]

Burcu et al did a study on 102 patients with head and neck cancer with the aim of investigating whether localization, side and stage of cancer, treatment type and radiotherapy dose have an effect on QOL. They found that the aforementioned characteristics did indeed have an effect on QOL and that QOL was lower in patients with advanced disease (stage III and IV) and treated with both surgery and radiotherapy. They also found that speech problems, mouth dryness, dysphagia and emotional disorders were the main factors affecting QOL. [37]

Disease stage and QOL were shown to have a high negative correlation as shown by Pusic et al [45] and Hammerlid et al [46]

Allen et al also studied the reliability and validity of the questionnaires using 123 patients with advanced head and neck cancer in different stages of treatment and found that the questionnaire displayed internal consistency as well as construct and discriminant validity and therefore endorsed its use in head and neck cancer. [47]

The EORTC QLQ C30 and H&N 35 questionnaires were utilised in a Spanish study on 109 patients according to tumour location, age, stage and treatment type and it was found that the questionnaires produced similar results as those in studies done in North and Central Europe. [38]

A cross cultural study on 200 patients was done in India, after pilot testing of the questionnaires and it was found that the EORTC QLQ C30 and H&N 35 questionnaires were both reliable and valid. [39]

5.0 STUDY JUSTIFICATION

There is no comprehensive study which has been undertaken in Kenya on the quality of life of patients with head and neck cancer. Understanding the effects of the presence of HNC and its sequelae provides the potential of designing interventions which will reduce the adverse impact of the disease process.

This study will assist physicians in detecting early changes in QOL of these patients and will also create the possibility of development of protocols to facilitate management of patients with head and neck cancer in terms of their quality of life at diagnosis, during and after treatment.

6.0 RESEARCH QUESTION

Does the presence of head and neck cancer affect the patient's quality of life?

7.0 HYPOTHESIS AND OBJECTIVES

NULL HYPOTHESIS

The presence of head and neck cancer has no effect on the quality of life of the patient

GENERAL OBJECTIVE

To determine the quality of life in patients with head and neck cancer at KNH presenting to the radiotherapy unit after diagnosis but prior to radiotherapy or chemotherapy.

SPECIFIC OBJECTIVES

1. To assess the reliability and validity of the EORTC-QLQ 30 and EORTC QLQ-H&N35 questionnaires in Kenyan head and neck cancer patients.
2. To determine whether age, gender, localisation, stage and prior treatment modality have an impact on the quality of life of the patient.

8.0 STUDY DESIGN

Descriptive cross sectional study

8.1 Calculation of sample size.

The sample size was estimated using the following formula:

$$N = \frac{Z^2 \sigma^2}{e^2}$$

n – Sample size

Z- 1.96 (95% confidence interval)

σ – Standard deviation of the mean score of the global QOL = 39.6

e – Desired level of the precision of the variance = 7

$$n = \frac{(1.96)^2 \times (39.6)^2}{7^2} = \frac{3.84 \times 1568.2}{49} = \frac{6021.88}{49} = 122.895$$

n = 123

8.2 Sampling method

Convenience sampling of patients was used.

All patients presenting to the radiotherapy department at Kenyatta National Hospital after a diagnosis of head and neck cancer, some of whom may have undergone surgical treatment prior to referral for radiotherapy but have not began radiotherapy or chemotherapy during the study period until the sample size is achieved.

8.3 Study duration

Three (3) months from the date of ethical approval.

8.4 Inclusion criteria

Age above 18 years

Patients with Stage 1-4 head and neck cancer (primary)

Patients who consent to participation in the study

8.5 Exclusion criteria

Presence of recurrent or secondary cancers

Patients who decline to participate in the study

Inability to understand the questionnaire due to cognitive and/or mental impairment

Presence of other head and neck disease e.g. Neck masses, Chronic Rhinosinusitis, Chronic Suppurative otitis media which already have an effect on the patient's QOL.

8.6 Study Limitations

There is currently no Kiswahili version of the EORTC questionnaires therefore patients who are not conversant in English may experience difficulties with the questionnaires.

9.0 MATERIALS AND METHODS

The EORTC QLQ C-30 (version 3.0) and the EORTC QLQ H&N 35 questionnaires were used in the study. The principal investigator took consent from the patients and explained the purpose of the questionnaires in face to face interviews. The study subjects filled in the questionnaires and the relevant data was extrapolated from the questionnaires. Those who were illiterate or did not understand English were assisted to fill in the questionnaires.

The EORTC QLQ C-30 scoring manual was utilised. The QLQ-C30 is composed of both multi-item scales and single-item measures. These include five functional scales, three symptom scales, a global health status / QOL scale, and six single items.

Each of the multi-item scales includes a different set of items; no item occurs in more than one scale. All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level.

Thus a high score for a functional scale represents a high / healthy level of functioning while a high score for the global health status / QOL represents a high QOL but a high score for a symptom scale / item represents a high level of symptomatology / problems.

The principle for scoring these scales is the same in all cases:

1. Estimate the average of the items that contribute to the scale; this is the *raw score*.
2. Use a linear transformation to standardise the raw score, so that scores range from 0 to 100; a higher score represents a higher ("better") level of functioning, or a higher ("worse") level of symptoms.

Data analysis

The raw data was analysed using SPSS 17.0 statistical software. The nonparametric Mann Whitney U and Kruskal Wallis tests were utilised for two samples and more than two samples respectively. Significance was established as $p < 0.05$.

Reliability

Internal consistency of the questionnaires was assessed using Cronbach's alpha co-efficient. Internal consistency describes the extent to which all the items in a test measure the same concept or construct and is therefore connected to the inter-relatedness of the items within the test.

The acceptable values of alpha range from 0.7 to 0.95. A low alpha value may indicate that some items have high variability or do not measure the same thing.

Validity

Criterion validity was assessed by comparing the overall scores obtained in this study with the EORTC reference values from the EORTC reference manual ^[48]

10.0 ETHICAL CONSIDERATIONS

The study was carried out after approval by the KNH/UON Ethics and Research Committee.

Only patients who gave informed consent were included in the study.

Confidentiality was maintained at all times and the participants did not incur any extra financial costs.

The participants were free to withdraw at any time if they so wished.

The principal investigator did not benefit in monetary terms from this study.

The results will be published to allow other medical practitioners to benefit from the study.

11.0 RESULTS

Reliability

The reliability co-efficient Cronbach's alpha was used to measure the reliability of the EORTC QLQ C30 and H&N 35 questionnaires. Acceptable values for reliability co-efficients should range from 0.70 to 0.95.

TABLE 1: RELIABILITY CO-EFFICIENTS FOR EORTC QLQ C30 AND H&N 35 SCALES

Variable	Items	Cronbach's alpha coefficient
<u>QLQ-C30</u>		
Global health status (QL2)	29, 30	0.857
Physical functioning (PF2)	1-5	0.891
Role functioning (RF2)	6, 7	0.932
Emotional functioning (EF)	21-24	0.618
Cognitive functioning (CF)	20, 25	0.645
Social functioning (SF)	26, 27	0.383
Fatigue (FA)	10, 12, 18	0.835
Nausea /vomiting (NV)	14, 15	0.619
Pain (PA)	9, 19	0.802
<u>QLQ-H&N35</u>		
Pain (HNPA)	31-34	0.605
Swallowing (HNSW)	35-38	0.584
Senses problems (HNSE)	43, 44	0.692
Speech problems (HNSP)	46, 53, 54	0.705
Trouble with social eating (HNSO)	49-52	0.659
Trouble with social contact (HNSC)	48, 55-58	0.632
Less sexuality (HNSX)	59, 60	0.923

For the QLQ C30, the scales that had alpha co-efficients of above 0.70 are global health status (0.857), physical functioning (0.891), role functioning (0.932), fatigue (0.835) and pain (0.802). These scores are within the acceptable range for Cronbach's alpha thus the QLQ C30

displayed acceptable internal consistency. With regard to the QLQ H&N 35, the scales that scored above 0.70 are speech problems (0.705) and less sexuality (0.923). The scales for pain (0.605), senses (0.692), social eating (0.695) and social contact (0.632) scored above 0.60 while the swallowing scales scored 0.584. While these scales do not meet the criteria for a 0.70 score they can still be considered acceptable ***

Validity

Criterion validity was assessed by comparing the overall median scores obtained from this study with the reference values in the EORTC QLQ reference manual. ^[48]

TABLE 2: QLQ C30 CRITERION VALIDITY MEDIAN SCORES COMPARISON BETWEEN STUDY PATIENTS AND EORTC REFERENCE VALUES

Variable	KNH study patients	EORTC Reference values
	Median (IQR)	Median (IQR)
GLOBAL HEALTH STATUS/QL2	50.0 (42.0-66.7)	66.7 [50-83.3]
FUNCTIONAL SCALES		
Physical functioning/PF2	74.0 (54.0-94.0)	86.7 [66.7-100]
Role functioning/RF2	67.0 (34.0-83.0)	100 [66.7-100]
Emotional functioning/EF	58.0 (41.7-83.0)	75 [58.3-91.7]
Cognitive functioning/CF	100.0 (67.0-100.0)	100 [83.3-100]
Social functioning/SF	83.0 (50.0-100.0)	100 [66.7-100]
SYMPTOM SCALES		
Fatigue/FA	44.4 (33.3-77.8)	22.2 [0-44.4]
Nausea and vomiting/NV	16.7 (0.0-33.3)	0 [0-0]
Pain/PA	33.3 (16.7-66.7)	16.7 [0-33.3]
SINGLE ITEM QUESTIONS		
Dyspnoea/DY	33.3 (0.0-66.7)	0 [0-33.3]
Sleep/SL	33.3 (0.0-66.7)	33.3 [0-33.3]
Appetite/AP	33.3 (0.0-66.7)	0 [0-33.3]
Cough/CO	0.0 (0.0-0.0)	0 [0-0]
Diarrhoea/DI	0.0 (0.0-0.0)	0 [0-0]
Financial difficulties/FI	100.0 (66.7-100.0)	0 [0-33.3]

Table 2 shows comparable results between the results obtained from this study and EORTC reference values thus confirming validity.

TABLE 3: QLQ H&N 35 CRITERION VALIDITY COMPARISON BETWEEN MEDIAN SCORES FOR STUDY PATIENTS AND EORTC REFERENCE VALUES

Variable	KNH study patients Median (IQR)	EORTC Reference values Median (IQR)
SYMPTOM SCALES		
Pain	8.3 (0.0-25.0)	25 [8.3-41.7]
Swallowing	8.3 (0.0-25.0)	16.7 [0-41.7]
Senses	16.7 (0.0-50.0)	0 [0-33.3]
Speech	33.3 (0.0-66.7)	22.2 [0-44.4]
Social eating	8.3 (0.0-25.0)	8.3 [0-33.3]
Social contact	13.3 (0.0-26.7)	0 [0-20]
Sexuality	33.3 (33.3-66.7)	16.7 [0-66.7]
SINGLE ITEM QUESTIONS		
Teeth	0.0 (0.0-0.0)	0 [0-33.3]
Mouth opening	0.0 (0.0-33.3)	0 [0-33.3]
Dry mouth	0.0 (0.0-33.3)	33.3 [0-66.7]
Sticky saliva	0.0 (0.0-33.3)	33.3 [0-66.7]
Cough	0.0 (0.0-33.3)	33.3 [0-66.7]
Feeling ill	66.7 (33.3-100.0)	0 [0-33.3]
Pain killers	100 (100-100)	0 [0-100]
Nutritional Supplements	0 (0-0)	0 [0-100]
Feeding tube	0 (0-0)	0 [0-0]
Weight loss	100 (100-100)	0 [0-100]
Weight gain	0 (0-0)	0 [0-100]

Table 3 compares the median scores for the QLQ H&N 35, the median scores were found to be comparable between the two thus confirming criterion validity for the data obtained.

The patient characteristics are as shown in Table 4.

TABLE 4:		
PATIENT CHARACTERISTICS		
PARAMETERS	n = 123	Frequency (%)
<u>GENDER</u>		
Female	31	25.2%
Male	92	74.8%
<u>AGE</u>		
Mean (SD)	53.5	13.5%
Range	19 - 81	
<u>LOCALISATION/SITE</u>		
Larynx	36	29.3%
Nasopharynx	24	19.5 %
Oral	18	14.6%
Oropharynx	18	14.6%
Hypopharynx	11	8.9%
Paranasal sinuses	8	6.5%
Salivary glands	7	5.7%
Nose	1	0.8%
<u>AJCC STAGE</u>		
1	6	4.9%
2	20	16.3%
3	25	20.3%
4	72	58.5%
<u>PRIOR TREATMENT</u>		
Yes (Surgery)	9	7.3%
No	115	92.7%

Thirty one (25.2%) were females while 92 (74%) were male. Mean age was 53.5 years. Of these, 36(29.3 %) had cancer of larynx, 24 (19.5%) had nasopharyngeal cancer, 18 (14.6%) had oral cancer, 18 (14.6%) had oropharyngeal cancer, 11(8.9%) had cancer of the hypopharynx, 8 (6.5%) had cancer of the paranasal sinuses, 7 (5.7%) had cancer of the salivary glands and 1(0.8%) had cancer involving the nose. Figure 1 illustrates graphically the percentage distribution according to tumour site.

Seventy two (58.5%) patients had stage 4 cancer, 25(20.3%) had stage 3 cancer, 20(16.3%) had stage 2 cancer and 6(4.9%) had stage 1 cancer. Figure 2 illustrates percentage distribution according to AJCC tumour stage. 115 (92.7%) of the patients had not had prior treatment/surgery and 9 (7.3%) had had surgery prior to their presentation in the Radiology department.

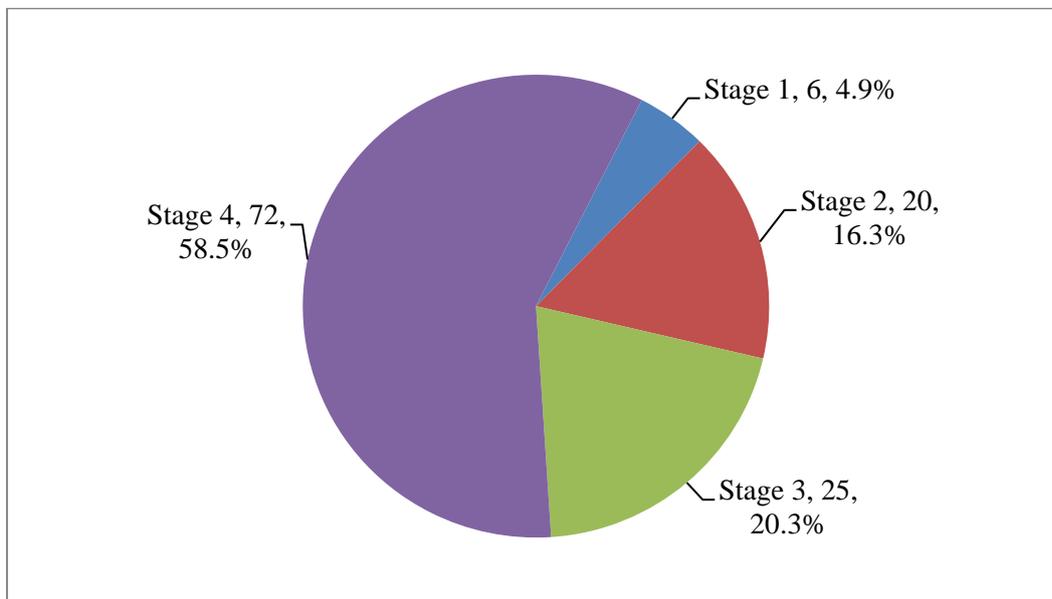


FIGURE 1: PIE CHART ILLUSTRATING PERCENTAGE DISTRIBUTION WITH REGARD TO TUMOUR STAGE

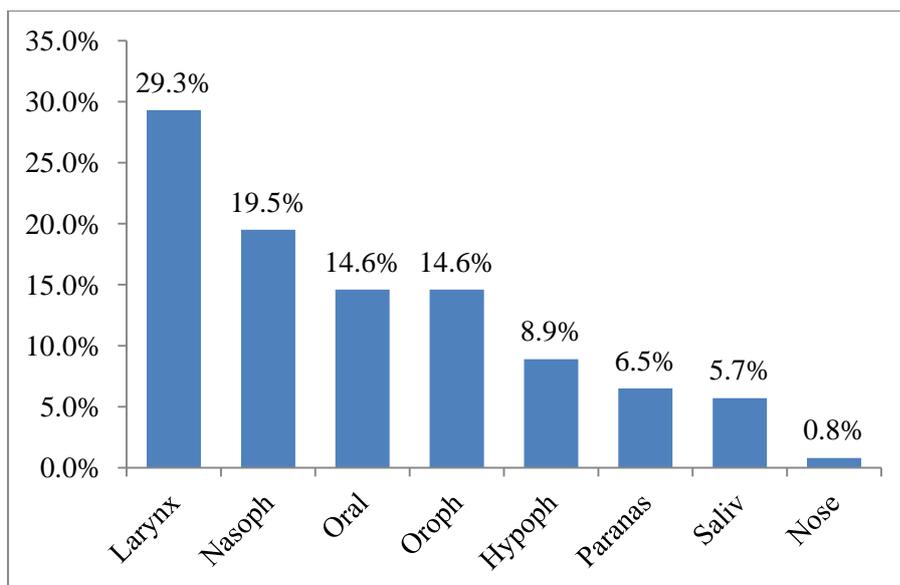


FIGURE 2: GRAPH ILLUSTRATING TUMOUR LOCALISATION IN PERCENTAGES

The results of the questionnaires' scales and single items were compared according to age, gender, AJCC tumour stage, tumour site/ localisation and effects of prior surgery.

Table 5 represents the EORTC QLQ C30 data in relation to gender.

TABLE 5: COMPARISON OF EORTC QLQ C30 IN RELATION TO GENDER (MANN WHITNEY U TEST)

Variable	Overall Median (IQR)	Female Median (IQR)	Male Median (IQR)	P value
QOL/ GLOBAL HEALTH STATUS	50.0 (42.0-66.7)	50.0 (41.7-66.7)	53.0 (42.0-66.7)	0.192
FUNCTIONAL SCALES				
Physical functioning	74.0 (54.0-94.0)	67.0 (54.0-87.0)	80.0 (54.0-94.0)	0.238
Role functioning	67.0 (34.0-83.0)	50.0 (17.0-67.0)	67.0 (34.0-83.0)	0.148
Emotional functioning	58.0 (41.7-83.0)	50.0 (25.0-67.0)	58.0 (50.0-84.0)	0.060
Cognitive functioning	100.0 (67.0-100.0)	83.0 (67.0-100.0)	100.0 (67.0-100.0)	0.694
Social functioning	83.0 (50.0-100.0)	83.0 (67.0-100.0)	83.0 (50.0-100.0)	0.628
SYMPTOM SCALES				
Fatigue	44.4 (33.3-77.8)	55.7 (34.0-77.8)	44.4 (16.7-77.8)	0.090
Nausea/ vomiting	16.7 (0.0-33.3)	16.7 (0.0-33.3)	0.0 (0.0-33.3)	0.671
Pain	33.3 (16.7-66.7)	33.3 (16.7-83.3)	33.3 (16.7-58.4)	0.452
SINGLE ITEM QUESTIONS				
Dyspnoea	33.3 (0.0-66.7)	0.0 (0.0-66.7)	33.3 (0.0-66.7)	0.254
Sleep	33.3 (0.0-66.7)	33.3 (0.0-66.7)	33.3 (0.0-66.7)	0.895
Appetite	33.3 (0.0-66.7)	33.3 (0.0-100.0)	33.3 (0.0-66.7)	0.341
Cough	0.0 (0.0-100)	0.0 (0.0-100.0)	0.0 (0.0-100.0)	0.598
Diarrhoea	0.0 (0.0-100)	0.0 (0.0-100.0)	0.0 (0.0-100.0)	0.805
Finances	100.0 (66.7-100.0)	100.0 (66.7-100.0)	100.0 (100.0-100.0)	0.668

For the QLQ C 30, male patients had an overall better QOL than the female patients as per the raw data but it was not statistically significant ($p= 0.192$). The male patients displayed better functioning on 4 out of 5 of the functional scales i.e. physical, role, emotional and cognitive as compared to the females but there was no statistically significant difference in any of those scales. The male and female cohorts had equal score social functioning.

The females experienced more fatigue, nausea and vomiting as compared to the males but there were no statistically significant differences. Both cohorts had an equal score with regard to pain, sleep, appetite, cough, diarrhoea but there were no statistically significant differences.

It was found that the male patients experienced more dyspnoea than the females though there was no statistically significant difference. None of the single item questions displayed any statistically significant difference.

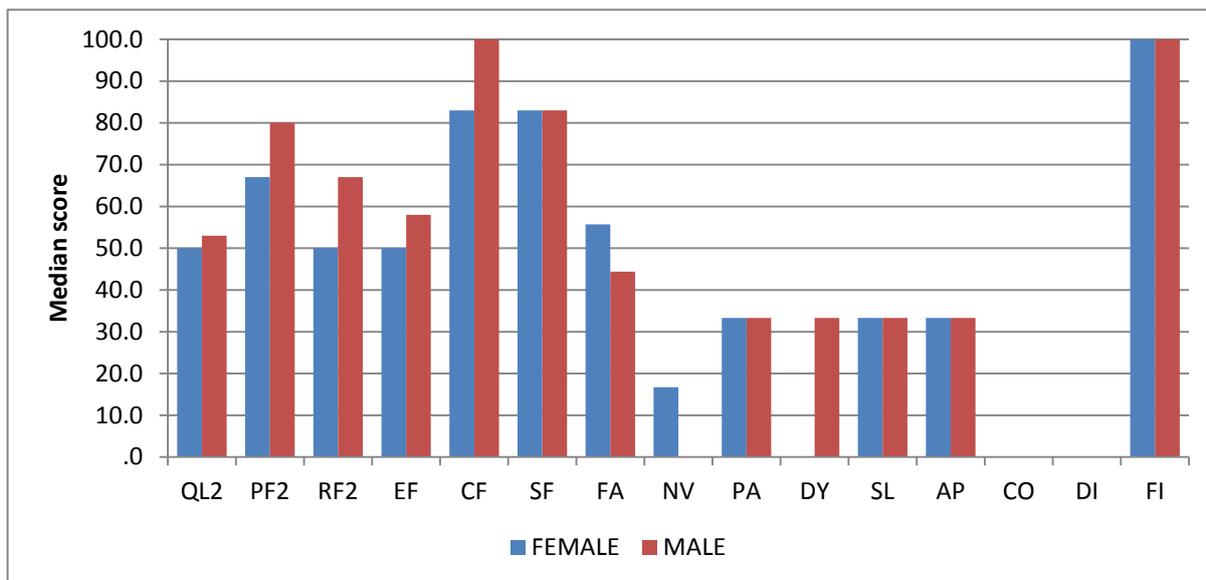


FIGURE 3: THE EORTC QLQ C30 MEDIAN SCORES ACCORDING TO GENDER

The scales are as follows: QL, Global Quality of life; PF, Physical functioning; RF, Role functioning; CF, Cognitive functioning; EF, Emotional functioning; SF, Social functioning; FA, Fatigue, NV nausea and vomiting; PA, Pain; DY, Dyspnoea; SL, sleep; AP, Appetite; CO, cough; DI, diarrhoea; FI, Financial difficulties; For PF to SF, higher scores reflect better functioning; for FA to FI higher scores indicate poor functioning. Significance was determined by Mann Whitney U tests. (Scales are not displayed if the medians for all groups equal 0.)

TABLE 6: COMPARISON OF EORTC QLQ H&N 35 IN RELATION TO GENDER (MANN WHITNEY U TEST)

Variable	Overall Median (IQR)	Female Median (IQR)	Male Median (IQR)	P VALUE
SYMPTOM SCALES				
Pain	8.3 (0.0-25.0)	8.3 (0.0-41.7)	8.3 (0.0-25.0)	0.553
Swallowing	8.3 (0.0-25.0)	8.3 (0.0-25.0)	8.3 (0.0-16.7)	0.373
Senses	16.7 (0.0-50.0)	0.0 (0.0-50.0)	25.0 (0.0-50.0)	0.536
Speech	33.3 (0.0-66.7)	0.0 (0.0-55.6)	44.4 (0.0-72.3)	0.022
Social eating	8.3 (0.0-25.0)	16.7 (0.0-33.3)	8.3 (0.0-25.0)	0.072
Social contact	13.3 (0.0-26.7)	13.3 (0.0-33.3)	13.3 (0.0-26.7)	0.785
Sexuality	33.3 (33.3-66.7)	50.0 (33.3-83.3)	33.3 (16.7-66.7)	0.389
SINGLE ITEM QUESTIONS				
Teeth	0.0 (0.0-100)	0.0 (0.0-33.3)	0.0 (0.0-100)	0.073
Mouth opening	0.0 (0.0-33.3)	0.0 (0.0-66.7)	0.0 (0.0-33.3)	0.146
Dry mouth	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.372
Sticky saliva	0.0 (0.0-33.3)	33.3 (0.0-66.7)	0.0 (0.0-33.3)	0.270
Cough	0.0 (0.0-33.3)	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.059
Feeling ill	66.7 (33.3-100.0)	66.7 (33.3-100.0)	66.7 (33.3-83.4)	0.653
Pain killers	100 (100-100)	100 (100-100)	100 (100-100)	0.314
Nutritional Supplements	0 (0-100)	0 (0-100)	0 (0-100)	0.744
Feeding tube	0 (0-100)	0 (0-100)	0 (0-100)	0.626
Weight loss	100 (100-100)	100 (0-100)	100 (100-100)	0.098
Weight gain	0 (0-100)	0 (0-100)	0 (0-100)	0.495

Table 6 compares the EORTC QLQ H&N 35 in relation to gender. The statistically significant differences are highlighted. The patients had equal scores for pain, swallowing and social contact with no statistically significant differences.

The male patients experienced more problems with senses (taste and smell) for which the difference was not statistically significant but there was a significant difference for speech (p=0.022) in which the males scored higher than the females.

The female patients had more difficulty with social eating and sexuality but this was not statistically significant (p= 0.785 and p=0.389). In the single item questions, the female patients were found to have suffered more from issues with sticky saliva (p=0.270) but there was no statistically significant difference.

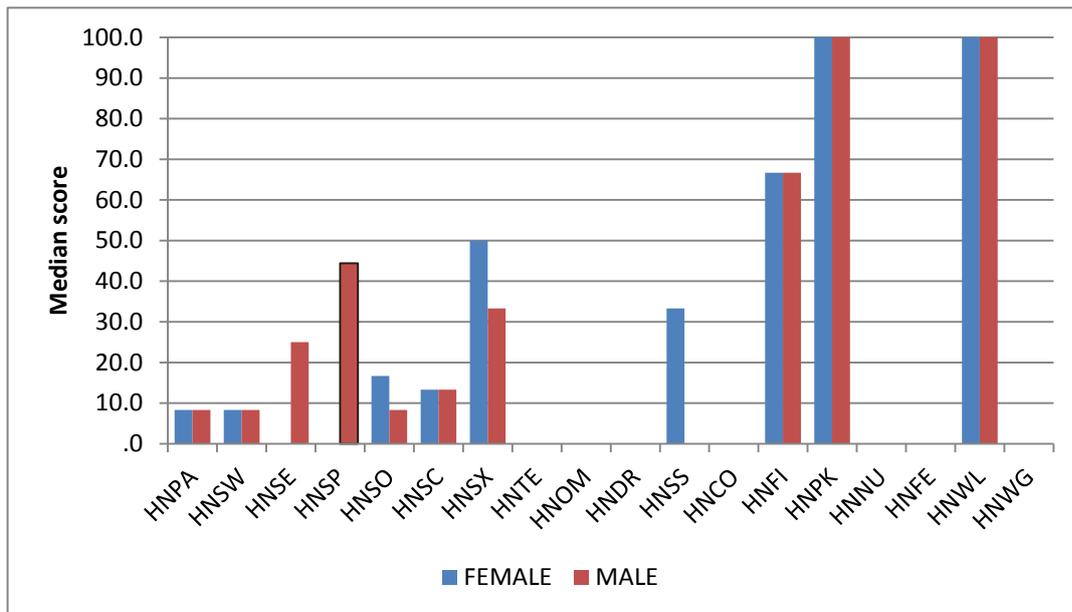


FIGURE 4: QLQ H&N 35 MEDIAN SCORES IN RELATION TO GENDER DIFFERENCES

The scales are as follows: HNPA, Pain; HNSW, Swallowing; HNSE, Senses; HNSP, Speech; HNSO, Social eating; HNSC, Social contact; HNSX, Sexuality; OM, Opening mouth; DR, Dry mouth; SS, Sticky saliva, CO, Coughed; FI, Felt ill; PK, Painkillers and WL, Weight loss. Higher scores indicate poorer functioning. Significance was determined by Mann Whitney U test. (Scales are not displayed if the medians for all groups equal 0.)HNSP is highlighted as it is statistically significant

TABLE 7: COMPARISON OF EORTC QLQ C30 IN RELATION TO PATIENT AGE (KRUSKAL WALLIS H TEST)

Variable	<45 years	45-59 years	>=60 years	P value
	Median (IQR)	Median (IQR)	Median (IQR)	
QOL/ GLOBAL HEALTH STATUS	66.7 (50.0-66.7)	50.0 (41.7-66.7)	50.0 (42.0-66.7)	0.090
FUNCTIONAL SCALES				
Physical functioning	87.0 (67.0-100.0)	60.0 (50.0-94.0)	70.5 (46.7-87.0)	0.064
Role functioning	67.0 (50.0-83.0)	50.0 (17.0-67.0)	67.0 (34.0-75.0)	0.126
Emotional functioning	50.0 (25.0-84.0)	58.0 (42.0-84.0)	58.0 (50.0-67.0)	0.233
Cognitive functioning	100.0 (67.0-100.0)	83.0 (67.0-100.0)	100.0 (75.0-100.0)	0.417
Social functioning	75.0 (50.0-100.0)	67.0 (50.0-100.0)	83.0 (67.0-100.0)	0.519
SYMPTOM SCALES				
Fatigue	44.4 (13.3-77.8)	55.7 (33.3-77.8)	44.4 (25.2-66.7)	0.372
Nausea/vomiting	16.7 (0.0-33.3)	0.0 (0.0-33.3)	0.0 (0.0-16.7)	0.085
Pain	33.3 (16.7-66.7)	33.3 (33.3-66.7)	33.3 (16.7-50.0)	0.327
SINGLE ITEM QUESTIONS				
Dyspnoea	0.0 (0.0-33.3)	0.0 (0.0-66.7)	33.3 (0.0-66.7)	0.233
Sleep	33.3 (0.0-33.3)	33.3 (0.0-66.7)	33.3 (0.0-66.7)	0.342
Appetite	33.3(0.0-66.7)	33.3 (0.0-100.0)	16.7 (0.0-66.7)	0.575
Cough	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.825
Diarrhoea	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.508
Finances	100.0 (66.7-100.0)	100.0 (66.7-100.0)	100.0 (100.0-100.0)	0.503

In relation to patient age, the EORTC QLQ C 30 (Table 7), the patients below 45 years of age had the best QOL when compared with the older patients($p=0.090$) thus a marginal statistical difference. In terms of physical functioning, those below 45 years of age had the best scores, while those between 45 to 59 years scored the lowest though there was no significant statistical difference($p=0.604$).

The patients aged 60 years and above had better emotional and social functioning than those aged 45 years and below but these scores were similar for the other two groups. These observations were not statistically significant ($p=0.233$ and $p=0.519$). The patients aged between 45 to 59 years had the lowest scores for role and social functioning but the differences were not statistically significant ($p=0.126$ and $p=0.519$).

For the symptom scales, patients aged below 45 years suffered from nausea and vomiting more often than the other two groups with no statistically significant difference ($p=0.372$ and $p=0.327$). With regard to the single item questions, the patients aged above 60 years experienced more dyspnoea than the other two groups with no statistically significant difference ($p=0.233$).

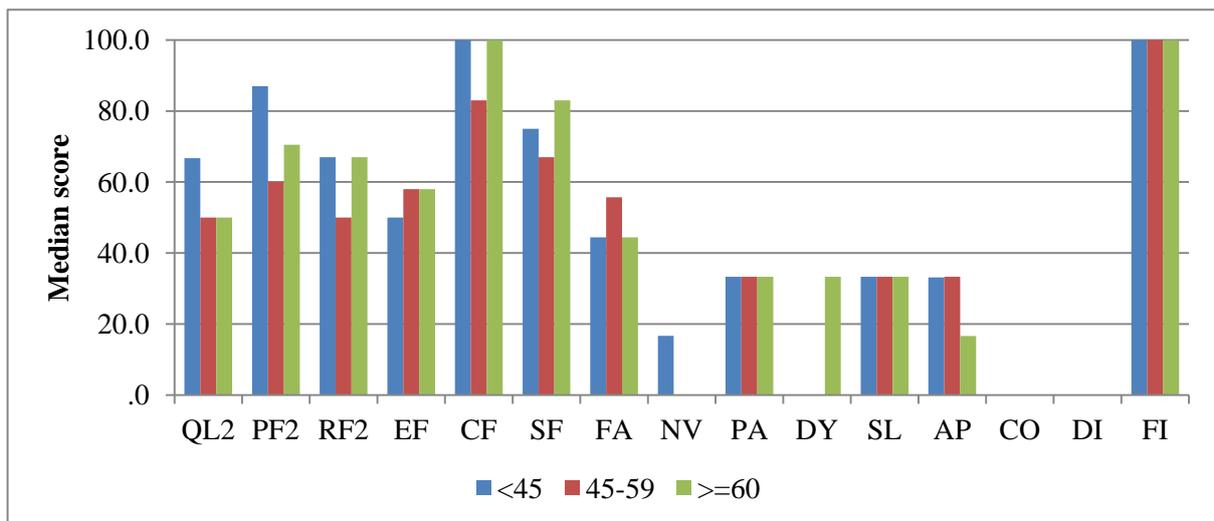


FIGURE 5: EORTC QLQ C30 MEDIAN SCORES IN RELATION TO AGE

The scales are as follows: QL2, Global Quality of life; PF, Physical functioning; RF, Role functioning; CF, Cognitive functioning; EF, Emotional functioning; SF, Social functioning; FA, Fatigue, NV nausea and vomiting; PA, Pain; DY, Dyspnoea; SL, sleep; AP, Appetite; CO, cough; DI, diarrhoea; FI, Financial difficulties; For PF to SF, higher scores reflect better functioning; for FA to FI higher scores indicate poor functioning. Significance was determined by Mann Whitney U tests. (Scales are not displayed if the medians for all groups equal 0.)

TABLE 8: COMPARISON OF EORTC QLQ H&N 35 IN RELATION TO PATIENT AGE (KRUSKALL WALLIS H TEST)

Variable	<45 years Median (IQR)	45-59 years Median (IQR)	>=60 years Median (IQR)	P value
SYMPTOM SCALES				
Pain	8.3 (0.0-33.3)	8.3 (0.0-16.7)	8.3 (0.0-25.0)	0.830
Swallowing	8.3 (0.0-16.7)	8.3 (0.0-25.0)	8.3 (0.0-20.9)	0.736
Senses	33.3 (0.0-83.3)	16.7 (0.0-50.0)	0.0 (0.0-33.3)	0.004
Speech	5.6 (0.0-55.7)	33.3 (0.0-66.7)	50.1 (0.0-72.3)	0.263
Social eating	16.7 (0.0-41.7)	8.3 (0.0-25.0)	4.2 (0.0-22.5)	0.154
Social contact	13.3 (0.0-33.3)	13.3 (0.0-33.3)	10.8 (0.0-22.5)	0.918
Sexuality	33.3 (0.0-50.0)	33.3 (33.3-100.0)	50.0 (33.3-66.7)	0.151
SINGLE ITEM QUESTIONS				
Teeth	0.0 (0.0-33.3)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.218
Mouth opening	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.0 (0.0-0.0)	0.282
Dry mouth	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.889
Sticky saliva	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.931
Cough	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.0 (0.0-0.0)	0.557
Feeling ill	33.3 (33.3-66.7)	66.7 (33.3-100.0)	66.7 (33.3-100.0)	0.271
Pain killers	100 (100-100)	100 (100-100)	100 (100-100)	0.851
Nutritional Supplements	0 (0-0)	0 (0-0)	0 (0-0)	0.452
Feeding tube	0 (0-0)	0 (0-0)	0 (0-0)	0.269
Weight loss	100 (100-100)	100 (100-100)	100 (50-100)	0.987
Weight gain	0 (0-0)	0 (0-0)	0 (0-0)	0.916

The comparison of the EORTC QLQ H&N 35 in relation to age is as shown above. The only statistically significant difference was for senses in the symptom scales ($p=0.004$). The patients aged 45 years suffered the most symptomatology with regard to senses followed by

those aged 45 to 59 years with those aged above 60 years had the lowest symptomatology with relation to senses.

The patients aged 60 years and above experienced more symptoms related to speech when compared with the other two groups, those aged between 45 to 59 years also experienced more speech related symptoms than those aged below 45 years but these differences were not statistically significant ($p=0.263$).

With regard to difficulties with social eating, the patients aged below 45 years experienced the greatest symptomatology followed by those aged between 45 to 59 years but there was no statistically significant difference ($p=0.154$). The patients aged above 60 years experienced the greatest symptomatology with regard to sexuality.

For the single item questions, the patients aged 45 years and below had fewer problems with feeling ill when compared to the other two groups though there was no statistically significant difference ($p=0.271$).

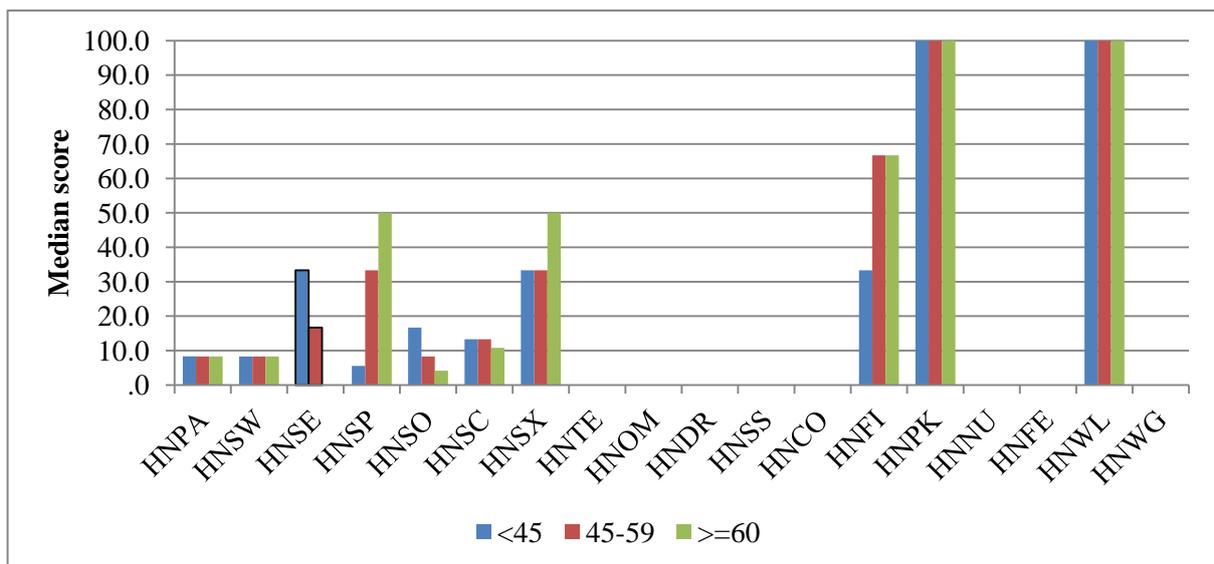


FIGURE 6: EORTC QLQ H&N 35 MEDIAN SCORES IN RELATION TO AGE

The scales are as follows: HNPA, Pain; HNSW, Swallowing; HNSE, Senses; HNSP, Speech; HNSO, Social eating; HNSC, Social contact; HNSX, Sexuality; OM, Opening mouth; HNDR, Dry mouth; HNSS, Sticky saliva; HNCO, Coughed; HNFI, Felt ill; HNPCK, Painkillers and HNWL, Weight loss. Higher scores indicate poorer functioning. Significance was determined by Kruskal-Wallis tests. (Scales are not displayed if the medians for all groups equal 0.) The senses scale is highlighted due to statistical significance ($p=0.004$)

**TABLE 9: COMPARISON OF EORTC QLQ C30 IN RELATION TO TUMOUR SITE/ LOCALISATION
(KRUSKALL WALLIS H TEST)**

VARIABLE	HYPOPHARYNX MEDIAN (IQR)	LARYNX MEDIAN (IQR)	NASOPHARYNX MEDIAN (IQR)	NOSE MEDIAN (IQR)	ORAL MEDIAN (IQR)	OROPHARYNX MEDIAN (IQR)	PARANASAL SINUSES MEDIAN (IQR)	SALIVARY GLANDS MEDIAN (IQR)	P VALUE
QOL/GHS	41.7 (33.3-50.0)	50.0 (42.0-66.7)	66.7 (50.0-66.7)	33.3	50.0 (50.0-66.7)	50.0 (42.0-75.0)	45.9 (40.9-75.0)	50.0 (42.0-66.7)	0.251
FUNCTIONAL SCALES									
Physical	54.0 (40.0-94.0)	67.0 (54.0-87.0)	85.5 (63.5-93.7)	27.0	82.0 (54.0-100.0)	82.0 (60.0-87.0)	52.0 (44.4-60.0)	100.0 (54.0-100.0)	0.160
Role	50.0 (0.0-67.0)	50.0 (34.0-67.0)	67.0 (67.0-91.7)	17.0	58.5 (34.0-67.0)	67.0 (34.0-100.0)	25.5 (17.0-50.5)	100.0 (34.0-100.0)	0.089
Emotional	58.0 (25.0-67.0)	58.0 (58.0-83.5)	58.0 (41.7-84.0)	25.0	58.0 (42.0-67.0)	58.0 (42.0-84.0)	33.4 (25.0-58.5)	50.0 (25.0-58.0)	0.269
Cognitive	83.0 (83.0-100.0)	100.0 (67.0-100.0)	91.5 (67.0-100.0)	100.0	91.5 (67.0-100.0)	100.0 (83.0-100.0)	67.0 (50.0-91.5)	100.0 (100.0-100.0)	0.261
Social	83.0 (50.0-100.0)	67.0 (50.0-91.5)	83.0 (58.5-100.0)	67.0	75.0 (67.0-100.0)	83.0 (67.0-100.0)	67.0 (67.0-83.0)	100.0 (67.0-100.0)	0.389
SYMPTOM SCALES									
Fatigue	66.7 (55.7-78.0)	44.4 (15.0-66.7)	39.2 (22.2-61.2)	88.0	66.7 (33.3-78.0)	55.7 (16.7-66.7)	55.7 (33.7-85.5)	33.3 (0.0-55.7)	0.068
Nausea/vomiting	33.3 (0.0-50.0)	0.0 (0.0-16.7)	16.7 (0.0-33.3)	0.0	16.7 (0.0-33.3)	16.7 (0.0-33.3)	13.9 (0.0-41.7)	0.0 (0.0-16.7)	0.112
Pain	50.0 (33.3-83.0)	33.3 (16.7-33.3)	50.0 (16.7-75.0)	83.3	33.3 (16.7-66.7)	50.0 (33.3-83.3)	50.0 (25.0-100.0)	16.7 (16.6-34.0)	0.049
SINGLE ITEM QUESTIONS									
Dyspnoea	66.7 (0.0-66.7)	66.7 (33.3-100.0)	0.0 (0.0-33.3)	33.3	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.0 (0.0-0.0)	0.0 (0.0-66.7)	<0.001
Sleep	33.0 (0.0-100.0)	33.3 (0.0-66.7)	33.3 (0.0-66.7)	100.0	16.7 (0.0-33.3)	50.0 (0.0-66.7)	49.9 (16.7-83.4)	0.0 (0.0-66.7)	0.400
Appetite	66.7 (33.3-67.0)	0.0 (0.0-33.3)	33.3 (0.0-100.0)	33.3	16.7 (0.0-66.7)	33.3 (0.0-100.0)	50.0 (0.0-100.0)	0.0 (0.0-66.7)	0.410
Cough	0.0 (0.0-66.7)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.100
Diarrhoea	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.751
Finances	100.0 (66.7-100.0)	100.0 (100.0-100.0)	100.0 (83.4-100.0)	100.0	100.0 (66.7-100.0)	100.0 (66.7-100.0)	100.0 (83.4-100.0)	100.0 (0.0-100.0)	0.997

Table 9 compares the EORTC QLQ C 30 in relation to tumour site.

Patients with nasopharyngeal cancer had the best QOL with those having nasal, paranasal and hypopharyngeal cancers displaying a poor QOL. Those with cancers of the larynx, oral cavity and oropharynx had average QOL, but there was no statistically significant difference for QOL ($p=0.251$)

In the functional scales, patients having salivary gland tumours displayed the best functionality in all scales except emotional functioning. The patients who had salivary gland cancers had the best physical functioning followed by those with nasopharyngeal, oral and oropharyngeal cancers. The patient with cancer of the nose had the worst physical functioning.

The patients with nasopharyngeal and oropharyngeal cancer had better role functioning than those with laryngeal, hypopharyngeal, nasal, oral and paranasal cancers though the difference was not statistically different.

In the symptom scales, the QLQ C30 was able to discriminate between the different tumour locations with significant differences for pain ($p=0.049$). In the single item questions, patients with hypopharyngeal and laryngeal tumours experienced more symptoms related to dyspnoea ($p < 0.001$). Patients with nasal, oropharyngeal and paranasal sinus tumours scored the worst with regard to ability to sleep while those with hypopharyngeal tumours exhibited poor appetite but there were no statistically significant differences.

TABLE 10: COMPARISON OF EORTC QLQ H&N 35 IN RELATION TO TUMOUR SITE (KRUSKAL WALLIS H TEST)

VARIABLE	HYPOPHARYNX MEDIAN (IQR)	LARYNX MEDIAN (IQR)	NASOPHARYNX MEDIAN (IQR)	NOSE MEDIAN (IQR)	ORAL MEDIAN (IQR)	OROPHARYNX MEDIAN (IQR)	PARANASAL SINUSES MEDIAN (IQR)	SALIVARY GLANDS MEDIAN (IQR)	P VALUE
SYMPTOM SCALES									
Pain	25.0 (0.0-41.7)	8.3 (0.0-16.7)	0.0 (0.0-8.3)	0.0	29.2 (8.3-41.7)	25.0 (8.3-41.7)	0.0 (0.0-16.7)	8.3 (0.0-16.7)	<0.001
Swallowing	41.7 (8.3-75.0)	4.2 (0.0-16.7)	0.0 (0.0-12.5)	0.0	15.0 (0.0-25.0)	16.7 (0.0-25.0)	0.0 (0.0-15.0)	8.3 (0.0-25.0)	0.023
Senses	0.0 (0.0-33.3)	0.0 (0.0-33.3)	66.7 (50.0-83.3)	66.7	8.4 (0.0-33.3)	0.0 (0.0-33.3)	58.3 (16.7-91.7)	0.0 (0.0-0.0)	<0.001
Speech	55.7 (11.1-78.0)	55.7 (44.4-78.0)	0.0 (0.0-38.8)	0.0	11.1 (0.0-55.7)	11.1 (0.0-78.0)	0.0 (0.0-22.2)	0.0 (0.0-78.0)	<0.001
Social eating	25.0 (16.7-50.0)	0.0 (0.0-8.3)	8.3 (0.0-29.2)	20.0	20.9 (6.7-33.3)	25.0 (0.0-33.3)	20.0 (0.0-37.5)	0.0 (0.0-13.3)	0.001
Social contact	20.0 (0.0-26.7)	16.7 (0.0-26.7)	7.5 (0.0-20.0)	16.7	6.7 (0.0-20.0)	6.7 (0.0-13.3)	23.3 (3.4-43.3)	13.3 (6.7-33.3)	0.740
Sexuality	50.0 (33.3-66.7)	33.3 (25.0-66.7)	33.3 (33.3-66.7)	100.0	41.7 (16.7-66.7)	41.7 (0.0-66.7)	83.4 (16.7-100.0)	50.0 (33.3-66.7)	0.737
SINGLE ITEM QUESTIONS									
Teeth	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.0 (0.0-16.7)	0.0 (0.0-0.0)	0.130
Mouth opening	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.0	33.3 (0.0-66.7)	33.3 (0.0-66.7)	0.0 (0.0-0.0)	0.0 (0.0-33.3)	<0.001
Dry mouth	0.0 (0.0-33.3)	0.0 (0.0-33.3)	33.3 (0.0-66.7)	0.0	0.0 (0.0-33.3)	0.0 (0.0-0.0)	33.3 (16.7-50.0)	0.0 (0.0-0.0)	0.005
Sticky saliva	0.0 (0.0-67.0)	0.0 (0.0-33.3)	33.3 (0.0-66.7)	0.0	33.3 (0.0-66.7)	0.0 (0.0-0.0)	33.3 (16.7-33.3)	0.0 (0.0-0.0)	0.014
Cough	33.3 (0.0-66.7)	0.0 (0.0-33.3)	0.0 (0.0-16.7)	0.0	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.0 (0.0-16.7)	0.0 (0.0-33.3)	0.333
Feeling ill	100.0 (66.7-100.0)	50.0 (0.0-66.7)	33.3 (33.3-66.7)	100.0	66.7 (33.3-100.0)	66.7 (33.3-66.7)	66.7 (33.3-83.4)	33.3 (33.3-100.0)	0.173
Pain killers	100 (100-100)	100 (100-100)	100 (100-100)	100	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)	0.196
Nutritional Supplements	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.755
Feeding tube	0.0 (0.0-100.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.331
Weight loss	100 (0-100)	100 (100-100)	100 (100-100)	0.0	100 (100-100)	100 (100-100)	50 (0.0-100)	0 (0-100)	0.057
Weight gain	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.793

When the EORTC QLQ H&N 35 was used in relation to tumour site (Table 10), statistically significant differences were seen for pain (p<0.001), swallowing (p=0.023), senses (p<0.001), speech (p=0.001), social eating (p=0.001), mouth opening (p<0.001), sticky saliva (p=0.014) and dry mouth (p=0.005).

Patients with oral, hypopharyngeal and oropharyngeal cancers experienced more difficulties with pain and swallowing than the other groups. Patients with cancers of the nose, nasopharynx and paranasal sinuses had greater symptomatology related to the senses (taste and smell).

With regard to speech, it was found that those patients who had hypopharyngeal and laryngeal cancers were most affected followed by those with oral and oropharyngeal cancers. With regard to difficulties with social eating, patients with cancers of the hypopharynx, oral cavity, oropharynx and paranasal sinuses had poor scores when compared to the other groups.

Patients with oral and oropharyngeal cancer had difficulties with mouth opening ($p < 0.0001$) while patients with nasopharyngeal, oral and paranasal sinus cancers experienced more symptoms related to sticky saliva ($p = 0.014$). Laryngeal cancer patients suffered most from cough.

TABLE 11: COMPARISON OF EORTC QLQ C30 IN RELATION TO AJCC TUMOUR STAGE

Variable	Stage 1	Stage 2	Stage 3	Stage 4	P value
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	
QOL/ GHS	66.7 (56.0-75.0)	66.7 (50.0-79.2)	50.0 (42.0-66.7)	50.0 (41.7-66.7)	0.005
FUNCTIONAL SCALES					
Physical functioning	100.0 (80.0-100.0)	87.0 (60.5-100.0)	80.0 (54.0-100.0)	67.0 (41.0-87.0)	0.003
Role functioning	100.0 (67.0-100.0)	67.0 (58.5-100.0)	50.0 (34.0-83.0)	50.0 (34.0-67.0)	0.010
Emotional functioning	46.0 (25.0-67.0)	58.0 (33.5-84.0)	58.0 (50.0-84.0)	58.0 (41.7-67.0)	0.728
Cognitive functioning	100.0 (100.0-100.0)	100.0 (83.0-100.0)	100.0 (67.0-100.0)	83.0 (67.0-100.0)	0.070
Social functioning	100.0 (83.0-100.0)	83.0 (67.0-100.0)	83.0 (67.0-100.0)	67.0 (50.0-83.0)	0.006
SYMPTOM SCALES					
Fatigue	44.4 (33.3-55.7)	55.7 (11.1-77.9)	44.4 (16.7-55.7)	50.0 (33.3-77.8)	0.604
Nausea/vomiting	8.4 (0.0-16.7)	16.7 (0.0-25.0)	16.7 (0.0-16.7)	0.0 (0.0-33.3)	0.978
Pain	25.0 (0.0-50.0)	33.3 (16.7-33.3)	33.3 (16.7-50.0)	33.3 (33.3-66.7)	0.105
SINGLE ITEM SCALES					
Dyspnoea	16.7 (0.0-33.3)	0.0 (0.0-50.0)	33.3 (0.0-66.7)	33.3 (0.0-66.7)	0.186
Sleep	33.3 (0.0-66.7)	16.7 (0.0-66.7)	33.3 (0.0-66.7)	33.3 (0.0-66.7)	0.537
Appetite	0.0 (0.0-0.0)	0.0 (0.0-50.0)	0.0 (0.0-66.7)	33.3 (0.0-100.0)	0.110
Cough	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.724
Diarrhoea	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.370
Finances	100.0 (66.7-100.0)	100.0 (100.0-100.0)	100.0 (66.7-100.0)	100.0 (100.0-100.0)	0.299

With regard to tumour stage, the QLQ C30 results are as shown in Table 11. Statistically significant differences were seen for QOL ($p=0.005$), physical functioning ($p=0.003$), role functioning ($p=0.010$), social functioning ($p=0.006$).

Patients with stage 1 and 2 cancer had a better QOL than those with stage 3 or 4 cancer ($p=0.005$). For the functional scales patients with stage 1 cancer had the best scores for physical, role, cognitive and social functioning but scored poorly for emotional functioning. Patients with stage 1 and 2 cancers had better physical and role functioning than those with stage 3 and 4 cancers ($p=0.003$ and $p=0.010$).

There was a marginal statistical difference for cognitive functioning ($p=0.070$) with stage 4 cancer patients having the lowest scores. Stage 4 patients scored the lowest for all functional scales except for emotional functioning.

For the symptom scales, Stage 2 and 4 patients experienced more fatigue while stage 2 and 3 cancer patients had more difficulties with nausea and vomiting.

With regard to the single item questions, patients with stage 3 and 4 cancers experienced more issues with dyspnoea, while stage 4 patients had difficulties with appetite but there were no statistically significant differences.

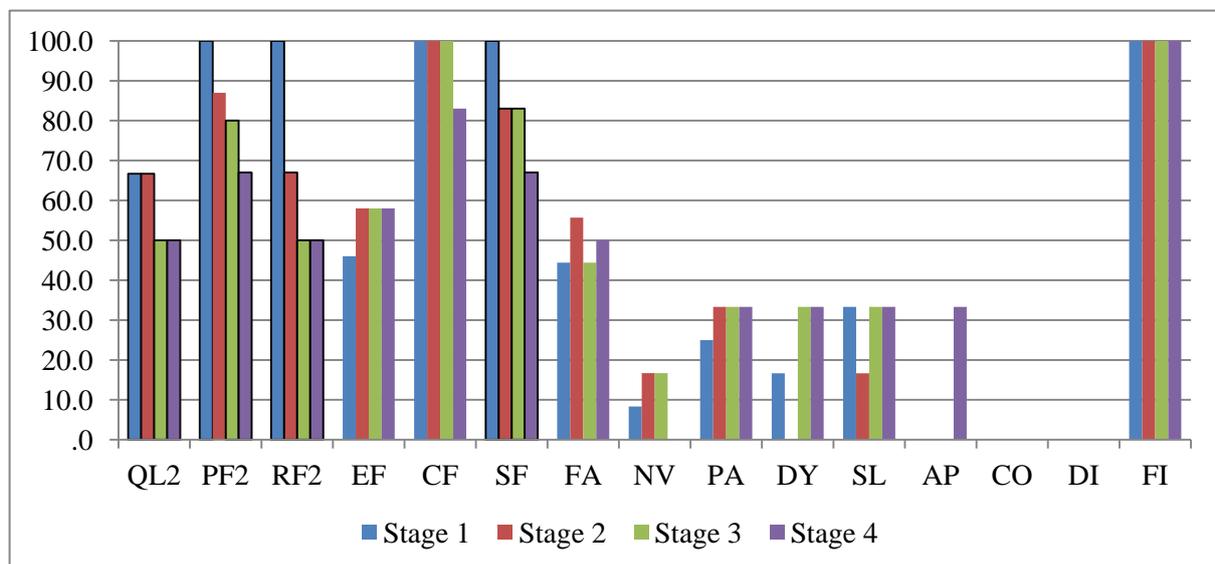


FIGURE 7: EORTC QLQ C30 MEDIAN SCORES IN RELATION TO TUMOUR STAGE

The scales are as follows: QL, Global Quality of life; PF, Physical functioning; RF, Role functioning; CF, Cognitive functioning; EF, Emotional functioning; SF, Social functioning; FA, Fatigue, NV nausea and vomiting; PA, Pain; DY, Dyspnoea; SL, sleep; AP, Appetite; CO, cough; DI, diarrhoea; FI, Financial difficulties; For PF to SF, higher scores reflect better functioning; for FA to FI higher scores indicate poor functioning. Significance was determined by Mann Whitney U tests. (Scales are not displayed if the medians for all groups equal 0). Highlighted scales are those which are statistically significant.

TABLE 12: COMPARISON OF EORTC QLQ H&N 35 IN RELATION TO TUMOUR STAGE (KRUSKAL WALLIS H TEST)

Variable	Stage 1 Median (IQR)	Stage 2 Median (IQR)	Stage 3 Median (IQR)	Stage 4 Median (IQR)	P value
SYMPTOM SCALES					
Pain	8.3(8.3-16.7)	4.2(0.0-29.2)	8.3(0.0-16.7)	8.3(0.0-25.0)	0.854
Swallowing	8.4(0.0-25.0)	4.2(0.0-8.3)	0.0(0.0-16.7)	8.3(0.0-25.0)	0.184
Senses	16.7(0.0-66.7)	33.3(0.0-41.7)	16.7(0.0- 33.3)	16.7(0.0-50.0)	0.989
Speech	38.8(0.0-78.0)	0.0(0.0-44.5)	11.1(0.0-66.7)	44.4(0.0-66.7)	0.153
Social eating	0.0(0.0-8.3)	4.2(0.0-20.9)	8.3(0.0-16.7)	12.5(0.0-33.3)	0.192
Social contact	0.0(0.0-13.3)	6.7(0.0-16.7)	6.7(0.0-20.0)	13.3(0.0-33.3)	0.063
Sexuality	33.3(16.7-33.3)	33.3(0.0-66.7)	33.3(33.3-66.7)	50.0(33.3-83.3)	0.065
SINGLE ITEM SCALES					
Teeth	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.276
Mouth opening	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.368
Dry mouth	33.3 (0.0-100.0)	0.0 (0.0-50.0)	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.324
Sticky saliva	16.7 (0.0-100.0)	0.0 (0.0-66.7)	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.868
Cough	16.7 (0.0-33.3)	0.0 (0.0-16.7)	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.327
Feeling ill	50.0 (33.3-100.0)	33.3(0-50.0)	66.7(33.3-66.7)	66.7(33.3-100.0)	0.016
Pain killers	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)	0.468
Nutritional Supplements	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.717
Feeding tube	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.501
Weight loss	100 (100-100)	100 (0-100)	100 (0-100)	100 (100-100)	0.615
Weight gain	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.592

In relation to tumour stage, the EORTC H &N 35 (Table 12), stage 2 patients suffered less pain swallowing and senses related difficulties than the other groups though the relationship was not statistically significant. With regard to speech, stage 4 patients had the highest scores, followed by stage 1 patients with no statistical difference.

Stage 4 cancer patients had poor scores with regard to social eating, social contact and sexuality. For the single item scales, stage 1 patients had the worst values for dry mouth,

cough and sticky saliva when compared with the other groups but p values were not statistically significant. There was a statistically significant difference for feeling ill (p=0.016) whereby stage 3 and 4 patients felt more ill than stage 1 and 2 patients.

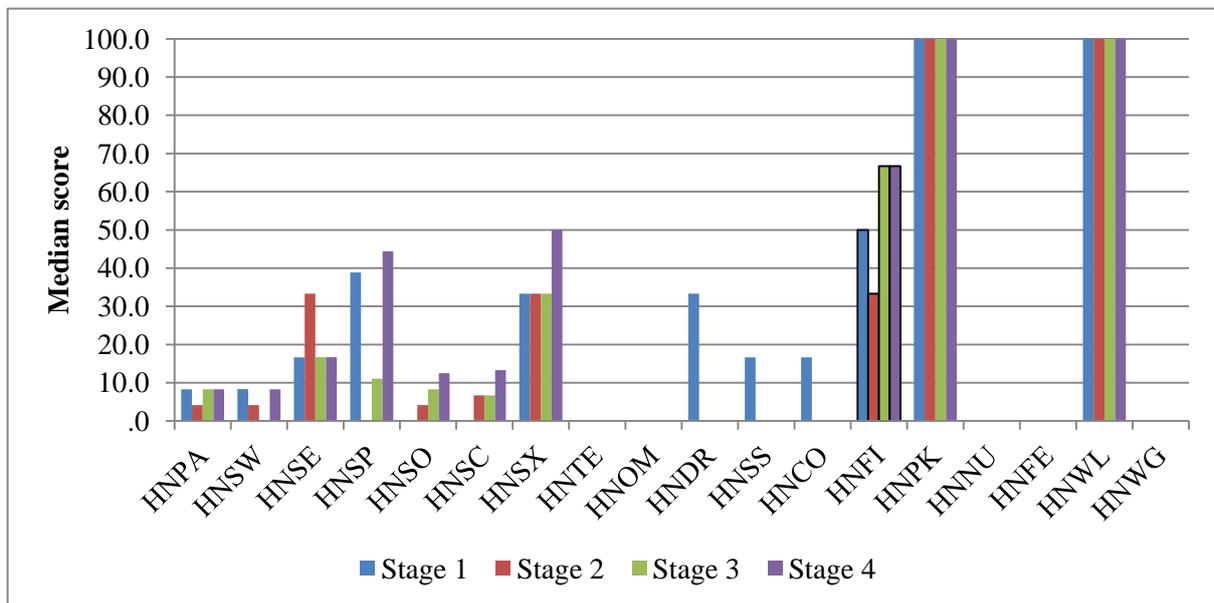


FIGURE 8: QLQ H&N 35 IN RELATION TO TUMOUR STAGE

The scales are as follows: HNPA, Pain; HNSW, Swallowing; HNSE, Senses; HNSP, Speech; HNSO, Social eating; HNSC, Social contact; HNSX, Sexuality; HNOM, Opening mouth; HNDR, Dry mouth; HNSS, Sticky saliva, HNCO, Coughed; HNF1, Felt ill; HNPk, Painkiller and HNWL, Weight loss. Higher scores indicate poorer functioning. Significance was determined by Kruskal-Wallis tests. (Scales are not displayed if the medians for all groups equal 0). Statistically significant differences for HNF1 (p=0.016)

TABLE 13: COMPARISON OF EORTC QLQ C30 IN RELATION TO PRIOR TREATMENT (MANN WHITNEY U TEST)

Variable	Prior treatment		P value
	Yes Median (IQR)	No Median (IQR)	
QOL/GHS	50.0 (50.0-75.0)	50.0 (42.0-66.7)	0.382
FUNCTIONAL SCALES			
Physical functioning	100.0 (80.0-100.0)	74.0 (54.0-87.0)	0.036
Role functioning	67.0 (17.0-100.0)	67.0 (34.0-83.0)	0.901
Emotional functioning	58.0 (50.0-58.0)	58.0 (41.7-83.0)	0.910
Cognitive functioning	100.0 (83.0-100.0)	100.0 (67.0-100.0)	0.421
Social functioning	83.0 (67.0-100.0)	83.0 (50.0-100.0)	0.422
SYMPTOM SCALES			
Fatigue	55.7 (44.4-78.0)	44.4 (33.3-66.7)	0.393
Nausea/vomiting	0.0 (0.0-16.7)	16.7 (0.0-33.3)	0.465
Pain	33.3 (16.6-50.0)	33.3 (16.7-66.7)	0.679
SINGLE ITEM SCALES			
Dyspnoea	0.0 (0.0-0.0)	33.3 (0.0-66.7)	0.011
Sleep	33.3 (0.0-66.6)	33.3 (0.0-66.7)	0.980
Appetite	0.0 (0.0-33.3)	33.3 (0.0-66.7)	0.212
Cough	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.858
Diarrhoea	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.523
Finances	66.7 (33.3-100.0)	100.0 (100.0-100.0)	0.026

With regard to prior treatment, the QLQ C30 (Table13), those who had undergone prior surgery had a similar QOL to those who had not had surgery though there was no statistically significant difference. Patients who had had prior surgery had better physical functioning than those who had not had surgery (p=0.036).

There was no significant statistical difference for the other functional scales. For the symptom scales, those who had surgery experienced more fatigue but less nausea and

vomiting. For the single item scales, the patients who did not have surgery experienced more dyspnoea than those who had surgery (p=0.011). The patients who did not have surgery had more financial problems than those who did not have surgery (p=0.026).

TABLE 14: COMPARISON OF EORTC QLQ H&N 35 IN RELATION TO PRIOR TREATMENT

VARIABLE	PRIOR TREATMENT	NO PRIOR TREATMENT	P VALUE
SYMPTOM SCALES			
Pain	8.3 (0.0-25.0)	8.3 (0.0-25.0)	0.832
Swallowing	8.3 (0.0-16.7)	8.3 (0.0-25.0)	0.621
Senses	0.0 (0.0-33.3)	25.0 (0.0-50.0)	0.208
Speech	0.0 (0.0-33.3)	33.3 (0.0-66.7)	0.119
Social eating	8.3 (0.0-16.7)	8.3 (0.0-25.0)	0.887
Social contact	13.3 (6.7-33.3)	13.3 (0.0-26.7)	0.597
Sexuality	50.0 (0.0-66.7)	33.3 (33.3-66.7)	0.721
SINGLE ITEM SCALES			
Teeth	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.476
Mouth opening	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.943
Dry mouth	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.050
Sticky saliva	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.044
Cough	0.0 (0.0-0.0)	0.0 (0.0-33.3)	0.063
Feeling ill	33.3 (33.3-66.7)	66.7 (33.3-100.0)	0.384
Pain killers	100 (100-100)	100 (100-100)	0.383
Nutritional Supplements	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.624
Feeding tube	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.956
Weight loss	0 (0-100)	100 (100-100)	0.024
Weight gain	0 (0-0)	0 (0-0)	0.468

In table 14, the H&N 35 was used to compare QOL in relation to prior treatment. Statistically significant differences were seen for dry mouth (p= 0.050), sticky saliva (p=0.044) and weight loss (p=0.024).

For the symptom scales, the patients who had not undergone surgery experienced more difficulties with senses and speech than those who had undergone surgery though there was no statistically significant difference.

There was a statistically significant result for dry mouth ($p= 0.05$). The patients who had not undergone surgery reported weight loss ($p=0.024$).

12.0 DISCUSSION

Improved medical research and technology has led to earlier diagnosis of cancer as well as effective and targeted treatment modalities. As such, quality of life has become an important component of patient care due to the symptoms associated with the various cancers, their treatment as well as the effects of these treatment modalities.

Due to their location, head and neck cancers are associated with disfigurement, interference with speech, swallowing and respiration. This can result in great social and emotional distress to the patient inadvertently affecting their quality of life.

In quality of life research, there is no questionnaire which has been certified as the gold standard. As per the literature review, there are various QOL questionnaires available for use in research. For this study the EORTC QLQ C 30 version 3.0 And the QLQ H&N 35 were utilised.

The EORTC QLQ-C30 questionnaire incorporates extensive QOL issues relevant to a broad range of cancer patients^[13-18]. It has been validated for many types of cancer including those of the head and neck.

The EORTC QLQ H&N 35 is a 35-item questionnaire that addresses HNC problems in seven subscales^[15, 26]. The EORTC QLQ H&N 35 is meant to be used with the QLQ-C30 in head and neck cancer patients.

The questionnaires performed well with regard to reliability, with the QLQ C30 displaying higher internal consistency than the QLQ H&N 35. The QLQ C30 scales were able to sufficiently discriminate between age, gender, tumour site and stage as well as prior treatment.

The QLQ H&N 35 scales were also able to distinguish between tumour site, age, gender, tumour stage and prior treatment. The QLQ H&N 35 did particularly well with regard to discriminating the patients according to tumour site. When used together, the two questionnaires were found to supplement each other but it was noted that they tapped into different dimensions of quality of life as was the intention.

The QLQ C30 and the QLQ H&N 35 were found to display sufficient criterion validity thus proving that they are valid.

In this study, male patients reported a better QOL than the female patients though this was not proven statistically. This can be explained by the fact that this study enrolled more males than females thus a higher score for the males.

The female patients tended to score worse in the functional scales i.e. emotional, role, cognitive and physical functioning. They also scored worse than the males with regard to fatigue, nausea and vomiting, social contact and sexuality though these differences were not statistically significant. The male patients experienced more dyspnoea probably due to the fact that all the patients who had cancer of the larynx (who formed 29.3% of the study population) were male and they reported dyspnoea as a major symptom.

Both the male and female patients experienced significant financial difficulties (despite the lack of statistical significance) which were related to the cost of carrying out lab tests and radiological and histological investigations as majority of the patients did not have health insurance thus had to pay out of pocket.

The male patients experienced more speech problems than the females which can be attributed once more to the fact that majority of the patients who reported voice problems were male patients with cancers of the larynx and hypopharynx, and speech problems are common with these tumour sub-sites.

Cough as a symptom was of statistical significance ($p=0.05$) due to the fact that the patients who reported cough as a major issue were those who had cancer of the larynx, hypopharynx and oropharynx and these subsites combined formed 58.5% thus cough as a symptom was prominent.

Patients below 45 years of age exhibited the best QOL and physical function when compared with those between 45 to 60 years and those above 60 years. The patients aged between 45 to 59 years had a better QOL than those aged more than 60 years. This suggests that perhaps better physical fitness and less co-morbidity (ies) in the younger patients as opposed to the effects of advancing age in the older patients has a role to play in quality of life and physical functionality.

Rodgers et al suggested that the correlation between age and some QOL variables is due to the natural course of life and age related comorbidity ^[49]

Patients below 45 years of age scored poorly with regard to emotional functioning when compared with the other two groups. This could be attributed to the fact that these patients by virtue of their age did not expect to be diagnosed with cancer thus were having a hard time emotionally, coming to terms with the reality of having cancer. The older patients on the other hand, probably had age related symptoms to which they were already accustomed and also by virtue of their age, a diagnosis of cancer was not totally unexpected.

The patients aged above 60 years experienced more dyspnoea than the other two groups (though not statistically significant); this can be attributed to lesser physical functionality, effects of cancer cachexia with regard to organ function and health status and also the fact that most of those aged above 60 years had cancers of the larynx, oropharynx and hypopharynx.

It was noted that patients aged below 45 years experienced more problems with senses (taste and smell) than those aged between 45 -59 years and above 60 years ($p= 0.004$). It is noteworthy that in this study population, nasopharyngeal and paranasal tumours were mainly affecting the younger patients and these tumours primarily affected smell and with that, taste.

Speech problems were more in the older population (not statistically significant $p=0.263$), and this is related to the tumour sub-sites of laryngeal, hypopharyngeal and oropharyngeal cancers which were seen in the older population.

Patients with tumours of the salivary glands appeared to have the best physical, role and social functioning which may be attributed to the fact that they suffered less symptomatology related to the tumour site. Also their tumours were diagnosed early due to the fact that they occurred in easily visible areas.

Laryngeal and hypopharyngeal cancer patients had significantly higher scores for dyspnoea which can be explained by the tumour site contributing to the symptoms. The mass effect of the tumours affected respiration and vocal function thus causing dyspnoea.

Pain was a statistically significant symptom ($p<0.001$), with patients with cancers of the larynx, oral cavity and oropharynx having the highest scores in that order. The location of tumour is significant in that the oral cavity and oropharynx have an important role to play in feeding, speech and respiration thus pain could not be ignored. Tumour size/stage had a role to play with regard to pain and cancer of the larynx as the larger the tumour was, the greater the pain.

Patients with cancer of the hypopharynx, oral cavity and oropharynx complained about swallowing difficulties more than the other patients ($p=0.023$) which is accounted for by the fact that these sites play an important role in passage of food thus the presence of tumour in these sites significantly affected feeding.

The patients who had cancers of the nose, nasopharynx and paranasal sinus tumours suffered most from symptoms related to the senses ($p<0.001$); this is significant because of the effects of these tumours on the nose, nasal mucosa and nasal function which in turn affects taste.

Speech problems mainly affected those patients with cancers of the larynx and hypopharynx ($p < 0.001$) because the presence of tumour in these sites affects respiration and voice function therefore affecting speech. The patients who had hypopharyngeal, oral cavity, oropharyngeal and paranasal sinus tumours had problems with social eating ($p = 0.001$); the symptoms caused by these tumours affected swallowing, chewing and also some of those with oral cavity and paranasal tumours had disfigurement thus explaining why these patients were reluctant to eat in public.

Patients with oral and oropharyngeal cancers had problems with mouth opening ($p < 0.001$), which was due to pain and trismus. Those with paranasal and nasopharyngeal cancers experienced dry mouths ($p = 0.005$) and sticky saliva ($p = 0.014$) as a result of mouth breathing due to nasal obstruction caused by the tumour location. Patients with oral cavity cancer also suffered from sticky saliva.

Only one patient had cancer of the nose and this patient scored poorly with regard to QOL, physical, role and emotional functioning. This patient had high scores for fatigue, pain, senses, sexuality and feeling ill. The tumour caused significant disfigurement thus giving the patient emotional lability as a result of physical appearance which contributed to issues of sexuality. The sense of smell was affected as a result of disfigurement that was caused by the disease process.

Other QOL studies had similar results for oral cancers which were found to have high symptom scores for pain, dental problems, dryness of the mouth, taste and smell. Hypopharyngeal and oropharyngeal cancers were also found to have higher scores for difficulty in swallowing, pain and sticky saliva. Laryngeal cancer patients suffered more from dyspnoea and speech problems. ^[50-57, 18]

The patients with stage 1 and 2 cancers had a better QOL than those with stage 3 and 4 cancers ($p = 0.005$), which is expected as the more advanced or larger the tumour, the greater the expected symptomatology. There is a negative co-relation between QOL and TNM staging in that the more advanced the cancer the worse the symptoms will be.

The patients with stage 1 and 2 cancers had better physical and role functioning than those with stage 3 and 4 cancers ($p = 0.003$ and $p = 0.010$ respectively) and this is attributed to the fact that the more advanced the cancer, the more symptoms and effects of cachexia. Also patients with advanced cancers tend to have a poor(er) nutritional status when compared with those with early cancers thus the physical and role functions are better in those with early cancers.

Patients with stage 1 cancer had poor emotional functioning when compared with the other stages (not statistically significant) which may be because due to the lesser symptomatology they did not expect a diagnosis of cancer and were having a harder time coping with the diagnosis.

Stage 1 and 2 cancer patients had better social functioning than those with stage 3 and 4 cancers perhaps because they experienced fewer symptoms and less disfigurement thus they were able to go out and socialise more as opposed to those who had more advanced tumours which caused disfigurement and were associated with greater symptoms thus these patients tended to stay at home and go out less.

Stage 4 patients had problems with appetite more than the other patients probably due to the nutritional issues and effects of advanced cancer on appetite.

Patients with stage 3 and 4 cancers felt more ill than those with stage 1 and 2 cancers which can be attributed to the effects of advanced cancers on nutritional status, organ function and general well being.

Hammerlid et al conducted a QOL study which found that patients with stage 3 and 4 cancers had higher scores/scale points for dental problems, senses, sticky saliva, difficulties with swallowing and feeling ill than stage 1 and 2 patients. ^[58]

Campbell et al also found that patients with advanced cancers were more likely to have low QOL scores with regard to disfigurement, ability to chew, speech and social eating. ^[50] Negative correlation between TNM staging and QOL has also been proven in other studies assessing QOL. ^[49, 59-63]

Pia- Lopez et al ^[38] concluded that the tumour stage at the time of diagnosis influenced the QOL more than age or sex, thus patients with advanced cancers required more intensive support than those with smaller tumours ^[64-67].

Patients who had undergone primary surgery prior to their presentation to the radiotherapy department had better physical functioning than those who had not undergone surgery ($p=0.036$). This is due to the fact that excision of the tumour essentially took away the symptoms and allowed these patients to feel better physically.

Dyspnoea as a symptom was more prominent in those patients who had not undergone surgery ($p=0.011$) probably because the presence of tumour was causing the dyspnoea unlike those who had undergone primary surgery who were now symptom free.

Dry mouth as a symptom displayed statistical significance ($p=0.050$) as well as weight loss ($p=0.024$). The patients who did not undergo surgery probably lost weight due to cancer cachexia and poor nutritional intake thus the statistical significance.

CONCLUSION

The QLQ C30 was found to be both valid and reliable. The QLQ C30 had good Cronbach's alpha score for majority of the scales. This questionnaire was also able to distinguish between the various tumour sites, gender, AJCC staging.

The QLQ H&N 35 was also found to be reliable and valid in its individual capacity and performed well in distinguishing between age, gender, AJCC staging and more so tumour location.

The two questionnaires worked well together in bringing out the various dimensions of QOL and together provided sufficient information with regard to the patients QOL.

The results obtained from this study were similar to those from other studies in which the EORTC QLQ C 30 and QLQ H&N 35 questionnaires were utilised. They proved to be effective tools in assessing the QOL of Kenyan head and neck cancer patients and as such their utility should be explored further.

Age and physical functionality has a role to play in QOL in that the natural course of life and co-morbidities associated with advancing age tend to reduce the QOL of the patients thus the reason why the younger patients were found to have a better QOL than the older patients

There is a negative co-relation between tumour stage and QOL; the more advanced the tumour the worse the symptoms and thus the poorer the QOL hence patients with stage 1 and 2 cancers had a better QOL than those with stage 3 and 4 cancers.

Tumour location has a significant role to play in QOL, as it determines the symptoms the patient experiences and QOL was found to decrease in a linear manner as symptom intensity increased.^[7]

RECOMMENDATIONS

Despite there being no gold standard QOL questionnaire, it would be of great value for the inclusion of QOL questionnaires in the management of patients with head and neck cancer as this will assist physicians in understanding the needs of their patients and how to respond to these needs.

Regular use of QOL instruments can be incorporated in the development of treatment protocols for head and neck cancer treatment in Kenya and this will put us in the forefront in head and neck cancer research.

Kiswahili translations of the EORTC questionnaires would be of great value for further QOL studies in Kenya as it was found that some patients had some difficulties with the English questionnaires. The translated versions should account for culturally acceptable norms and practices as some of the questions especially those related to sexuality were not well received by the patients.

Due to the fact that the EORTC questionnaires have by virtue of this study been found to be both valid and reliable, they should be further utilised in patient management pending the translation of a Kiswahili version.

Early diagnosis and treatment of head and neck cancer will significantly improve the QOL of Kenyan patients with this disease thus improving their overall health and perhaps life span.

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14.0 APPENDIX

14.1 GENERAL PATIENT INFORMATION AND CONSENT FORM

My name is Dr. Marianne Gitau. I am carrying out a study on the quality of life of patients with head and neck cancer and would like to seek your consent and participation in this study. I have received authorisation from the KNH/UON Ethics and Research committee to carry out this study.

The main objective of this study is to assess the quality of life in patients with head and neck cancer i.e. to determine how the presence of head and neck cancer affects your daily life and activities as compared to your quality of life prior to the cancer. I will give you questionnaires to fill in, and the information gathered from these questionnaires will assist me in the study.

How to participate

1. Give consent
2. Fill in a questionnaire which contains several questions about your condition and how it has affected your daily life.

How will your participation affect/benefit you?

There is no adverse effect in participating as:

1. You will receive the same treatment whether or not you participate in this study
2. Any information you give will remain confidential.
3. You are free to withdraw from the study when you wish

How will your participation aid this study?

1. The findings of this study will facilitate management of patients with head and neck cancer and in future, the development of treatment protocols.
2. The results will be shared with other medical professionals via medical journals or at scientific conferences without divulging confidential information.

If you understand and accept the above information then you can sign the consent form below.

I Mr/Ms/Mrs _____, having read and understood the above information have agreed to participate in this study as explained to me by Dr M. Gitau. My signature as appended below is proof of my consent. I also confirm that I have not received any material or monetary gain as a result of my participation.

Signature of participant

Date

Principal Investigator

Date

CONTACTS:

1. Dr Marianne Gitau (Principal Researcher)
Department of Surgery, UON
Tel no: 0722751354
Email mgitau@students.uonbi.ac.ke
2. KNH/UON Ethics and Research Committee (ERC)
Tel no: +2542726300-19 Ext.44102
P O BOX 20723-00202, Nairobi, Kenya
Email: uonknh_erc@uonbi.ac.ke

MAELEZO YA UTAFITI NA KIBALI CHA UTAFITI

Jina langu ni Daktari Marianne Gitau. Ninafanya utafiti unaotekeleza jinsi kuwepo kwa ugonjwa wa saratani unadhuru maisha ya wagonjwa walioathirika na ugonjwa huu wa saratani. Nimepatiwa ruhusa na Kamitii inayosimamia maswala ya utafiti katika hospitali ya Kenyatta na Chuo kikuu cha Nairobi yaani KNH/UON ERC.

Shabaha kuu ya utafiti huu ni kutathmini jinsi kuwepo kwa ugonjwa wa saratani kumebadilisha maisha yako ya kila siku tukilinganisha na maisha yako kabla upatikane na ugonjwa wa saratani. Nitakupa dodoso ambayo utajaza na takwimu ambayo nitapata kutokana na dodoso hio itatumika kwa utafiti huu.

Nitashiriki aje kwa utafiti huu?

1. Upatiane kibali cha kushiriki
2. Utajaza dodoso ambayo itakuwa na maswali kadhaa yanayohusu ugonjwa wa saratani na jinsi ugonjwa huu umekudhuru.

Ushiriki wako utakuathiri aje ?

1. Hakuna matokeo tofauti hata ukikosa kukubali kushiriki kwa utafiti huu.
2. Habari yeyote ambayo utapatiana itabaki siri kati yako na mimi
3. Uko huru kujitoa kwenye utafiti huu wakati wowote utakayo

Ushiriki wako utafaidi aje utafiti huu?

Matokeo ya utafiti huu utasambazwa kwa matabibu wataalamu kutumia majarida na mikutano ya kisiansi ili kuwezesha ueneaji wa maarifa katika matibabu ya saratani ya kichwa na shingo.

Kama umeelewa na umekubali habari ambayo umesoma basi patiana kibali chako hapa:

Mimi Bw/Bi/Binti _____, nimesoma maelezo yanayohusu utafiti huu kama nimevyoelezwa na Daktari M. Gitau na nimekubali kushiriki katika utafiti huu. Sahihi yangu ni udhibitisho wa ridhaa yangu.

Sijapatiwa fedha wala nyenza yeyote ili nishiriki katika utafiti huu.

Sahihi ya Mshiriki

Tarehe

Sahihi ya Mpelelezi Mkuu

Tarehe

1. Dr Marianne Gitau (Mpelelezi Mkuu)
Department of Surgery, UON
Simu: 0722751354
Barua pepe: mgitau@students.uonbi.ac.ke
2. KNH/UON Ethics and Research Committee (KNH/UON ERC)
Simu: +2542726300-19 Ext.44102
P O BOX 20723-00202, Nairobi, Kenya
Barua pepe: uonknh_erc@uonbi.ac.ke

14.2 PATIENT BIO- DATA SHEET

INITIALS: _____

IP NUMBER/
RT NUMBER: _____

AGE: _____

GENDER: M F

TUMOUR LOCATION: LARYNX
 : NASOPHARYNX
 : ORAL
 : OROPHARYNX
 : PARANASAL SINUSES
 : SALIVARY GLANDS
 : HYPOPHARYNX
 : NECK
 : OTHER (state) _____

TNM STAGING : STAGE I
 : STAGE II
 : STAGE III
 : STAGE IV

TREATMENT : NO SURGERY
 : PRIMARY SURGERY

