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ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF PHARMACY
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**Heath Related Quality of Life, Predictors and Utility
among Patients with Cervical Cancer in Tikur
Anbessa Specialized Hospital, Addis Ababa, Ethiopia**

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**Health Related Quality of Life, Predictors and Utility
of Cervical Cancer Patients in Tikur Anbessa
Specialized Hospital, Addis Ababa, Ethiopia**

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This is to certify that the Thesis prepared by Liya Teklu entitled: **Health Related Quality of Life, Predictors and Utility among Patients with Cervical Cancer in Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia** and submitted in partial fulfillment of the requirements for the degree of Master of Science in Pharmacoepidemiology and Social Pharmacy complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Acronyms

ADR	Adverse drug reactions
ECOG-PS	Eastern Cooperative Oncology Group Performance Status
EORTC QLQ-CX24	European Organization for Research and Treatment of Cancer Quality of life questionnaire- Cervical cancer Module
EORTC QLQ-C30	European Organization for Research and Treatment of Cancer Quality of life questionnaire- Core
EQ5D-5L	Euro Quality of Life Groups 5-domain, 5-level Questionnaires
EQ-VAS	Euro Quality of Life Group's visual scale analog
FACT-G	Cancer specific Functional Assessment of Cancer Therapy-General
FACT-CX	Cancer specific Functional Assessment of Cancer Therapy-Cervical Cancer Specific
FIGO	International Federation of Gynecology and Obstetrics
GLOBCAN	Global Cancer Initiative
GQOL	Global Quality of Life
HADS	Cancer specific Hospital and Anxiety Depression Scale
HRQOL	Health Related Quality of Life
HIV	Human Immunodeficiency Virus
POMS	Generic Profile of Mood States
QALY	Quality Adjusted Life Year
QOL	Quality of Life
RSCL	Cancer specific Rotterdam Symptom Checklist
SF-36	Short Form 36
TASH	Tikur Anbessa Specialized Hospital
VAS-C	Cancer specific Visual Analogue Scale-Cancer

Abstract

Background: Cervical cancer is the second most prevalent malignancy in Ethiopia associated with high mortality and morbidity. It is costly to manage the disease and it severely affects women's health-related quality of life (HRQOL). Nonetheless, few efforts have been made to assess the patients' HRQOL, its predictive factors and their utility values set in Ethiopia. As a result, decisions on cost-effective interventions still remains on personal experiences and evidences from other countries, without doing a formal economic Assessment locally.

Objective: To validate the Amharic version of European Organization for Research and Treatment of Cancer-Cervical Module (EORTC QLQ-CX24), assess Health Related Quality of Life, its associated factors and utility of cervical cancer patients in Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

Methods: An institutional based cross-sectional study was conducted in Tikur Anbessa Specialized Hospital from January to June, 2018. A total of 404 cervical cancer patients were interviewed using the Amharic version of; European Organization for Research and Treatment of Cancer module (EORTC QLQ-C30), EORTC QLQ-CX24 and Euro Quality of Life Group's 5-Domain Questionnaires 5 Levels (EQ 5D 5L) and Euro Quality of Life Group's visual scale analog instruments (EQ-VAS) tools. The Amharic versions of all Instruments were previously validated except for the Amharic version of EORTC QLQ-CX24 which was used in the present study through forward and backward translation approach and validated by interviewing 171 cervical cancer patients prior the data collection for the main study. The data was analyzed using SPSS version 23 and Microsoft Office Excel 2010. Pearson correlation, Cronbach's alpha and independent t-test, were employed to assess the reliability and validity of EORTC QLQ-CX24 while; ANOVA and stepwise multivariable logistic regression were employed to determine mean difference and significant associations.

Results: The EORTC QLQ-CX24 was found to be acceptable with high compliance and low missing response. The Cronbach's alpha ranged from 0.70-0.837, indicating reliability of the scale. Convergent and discriminant validity in multi-trait scaling analyses was adequate. The tool also confirmed its clinical validity by differentiating among groups and concurrent validity by the weak to strong correlation with EORTC QLQ-C30.

In the HRQOL assessment, the mean age of patients was 52.092 ± 0.50 years and majority (93.8%) of the patients were treated as outpatients. The highest proportion (35%) of patients, were on FIGO stage IV of cervical cancer. The Mean \pm SD Global quality of life of patients (GQOL) was 48.3 ± 23.77 , while the EQ VAS mean score was found to be 65.7 ± 20.83 . Social functioning and sexual activity scored the lowest mean from the functioning scales, while financial difficulty, pain and fatigue scored the highest mean from the symptom scales. Physical functioning (AOR=4.98, 95%CI=2.16-11.49), emotional functioning (AOR=5.25, 95%CI=2.26-12.17), pain (AOR=5.79, 95%CI=2.30-14.57) and symptom experience (AOR=4.58, 95%CI=1.95-10.79) had a strong association with the GQOL of patients. The utility value was found to be 0.7.

Conclusions: Cervical cancer patients reported poor HRQOL and above average utility score. Hence, strong psychological support, pain management and awareness creation including their care takers and partners should be included in the management of this patient group. The Amharic version of the EORTC QLQ-CX24 questionnaire can be used as an acceptable, reliable and efficient tool in clinical use and clinical research to assess the HRQOL of cervical cancer in Ethiopia.

Key words: Cancer, Cervical cancer, Validation, Health related quality of life, HRQOL, Utility, EQ5D-5L, EORTC QLQ-C30, EORTCQLQ-CX24, Ethiopia

1. Introduction

1.1. Background

Cervical cancer is disease in which the cells of the cervix start to grow uncontrollably, forming tumors like most cancerous cells. This abnormal growth could arise from different predisposing factors or previous exposure to risk factors such as multiple sexual partners, early onset of sexual intercourse, history of cigarette smoking, a male sexual partner who has had many sexual partners, family history of cancer and the major one being, Human papilloma virus infections. This exposure through 5-10 years will transform the normal cells to dysplastic cells, which will then progress to the in-situ carcinoma followed by the development of clinical cervical cancer (American cancer society, 2012).

A study done on global burden of cancer indicates that women are highly affected by certain cancers than others (GLOBCAN, 2017). In low resource countries of sub-Saharan Africa, cervical cancer, has the second highest incident cases and cause of death in women (GLOBCAN, 2017). WHO also released a report that stated, populations in Ethiopia, Zimbabwe, Malawi, and Uganda all have extremely high rates of cervical cancer, whereas many populations in the USA, Europe, and North Africa have rates that are 10 times lower (WHO, 2013). Currently in Ethiopia, cervical cancer screening is one measure being taken by the government in order to capture the disease at its earliest stage. However, with only one radiotherapy center, distribution of treatment is still imbalanced with the disease burden (FMOH, 2015).

Cervical cancer staging is usually described in terms of a staging scheme developed by the International Federation of Gynecology and Obstetrics (FIGO) Stage I to IV with sub stages; Stage IV indicating the late stage of the disease (American Cancer Society, 2012). Mandatory tests such as Speculum, vaginal and rectal examination, Intravenous pyelogram (IVP) or abdominal ultrasound and some supplementary tests could be done like Cystoscopy, Proctoscopy, Cone biopsy, Endo-cervical curettage or smear, Chest X-ray, Skeletal X-ray or bonescan if bone pain is reported, Blood tests, CT scan and kidney and liver function tests are recommended by professionals (WHO, 2014).

Main stay of treatment for cervical carcinoma is dependent on the clinical stage of the cancer. Patient's willingness, economic and social responsibilities of the person, will eventually affect the adherence to treatment. These treatment options should also be under the consultation of the right specialists such as the gynecologists, oncologist and radio therapy specialists. International guidelines put Surgery, radiotherapy and chemotherapy as main stay of treatment in invasive carcinoma all of which have a minor to major side effect and complications (WHO, 2014).

Health Related Quality of Life (HRQOL) is a wellbeing that can be related to or affected by the presence of a disease or treatments (Fayer and Machin, 2007). Cervical cancer affects the HRQOL of women from the diagnosis stage to treatment. It was noted that the cervical cancer affects the body image, sexual activity of patients in addition to the social and physical functioning (Bae and Park, 2016). High levels of anxiety and depression are also observed in patients diagnosed with cervical cancer (Herzog and Wright, 2007). HRQOL can be measured by different validated tools that assess the functioning, symptoms, psychological wellbeing and social support. In addition to measuring the HRQOL of patients, utility values set is commonly used to make evidence-based decision in analysis of cost-effectiveness (Gusi *et al.*, 2010). Different instruments to capture patient reported outcome are available; EQ5D 5L is one instrument to measure preference-based health status. Using validated tools assures the reliability and validity of the measurement questionnaire to a specific community in their local language (Grimelet *et al.*, 2009). Measurement of the HRQOL of patients allows clinicians to have a better understanding of patient's status and eventually make decisions that could lead to a better health outcome for the patient (Whitehead and Ali, 2010).

However, there are very few or no information in regards to the HRQOL or Utility of the cervical cancer patients in Ethiopia. The main aim of this study was, therefore, to assess the HRQOL and utility of cervical cancer patients using validated Amharic version questionnaires. It also endeavors to assess the predictive factors associated to the HRQOL providing a comprehensive understanding on the status of cervical cancer patients attending Tikur Anbessa Specialized Hospital (TASH). As EORTC QLQ CX-24 does not have a validated Amharic version, this research also aims to validate the tool. The availability of this data would help the decision making of health care professionals and policy makers on the steps to take in order to bring cost effective and efficient treatment alternatives specific to this group of patients.

1.2. Statements of problem

Cervical cancer is the second most prevalent cancer in women aged between 15 to 44 years worldwide (HPV Information Center, 2017). Studies also indicated that estimates of 527,624 women are diagnosed with cervical cancer each year and 265,672 dies from it (WHO, 2013). Cervical cancer was the most common cause of cancer deaths for women in 50 countries in the world and the most diagnosed cancer for women in 11 countries; Sub-Saharan countries including Ethiopia falling in this category (GLOBCAN, 2017).

As a major public health problem in Ethiopia, the disease affects the country's vulnerable demographic i.e. those who have poor health care, those with minimal education, rural communities with low activities and knowledge of screening and those with biological risk factors such as HIV. It is highly likely that one develops cervical cancer if not treated in its early stage (FMOH, 2015). About 80% of reported cases of cancer are diagnosed at advanced stages, when very little can be done to treat the disease. Currently there are diligent efforts to promote early detection and screening (HSTP, 2015).

In Ethiopia, the treatment options and infrastructures are not adequate for the cases that come about. Management options are not always available within the health care system. The treatments options such as radiation are only available in one hospital, TASH, and the waiting period is more than six months (FMOH, 2015). Only patients with the resources have the opportunity to seek early treatment abroad. These problems with access to health care adds on to the patient's mental distress and also enables the progression of the disease as they wait for treatment (NCCPCIP, 2015).

Cervical cancer has a major effect on a patient's quality of life and it is known that this includes physiological and psychological impact. The anxiety, discomfort, insecurity and loss of sexual desire in cervical cancer patients have stood out more than others (Torkzahraniet *al.*, 2013, Tadele, 2015). Cervical cancer patients also tend to have issues involving their femininity, self-image, and changes in sexual function in addition to the general distress that follows cancer treatment (Matushtia *et al.*, 2005, Ljuca and Marosevic, 2009,).

Determining HRQOL is associated with the survival benefit that a pharmacological treatment may provide (Abate,2015). The assessment, will also allow a better decision making in terms of treatment alternatives and better outcome for patients. In order to introduce the cost-effective interventions and anchor the decision making, Utility measurements are one appropriate method of conducting economic evaluations (Whitehead and Ali, 2010). Despite the burden of disease and limited financial resources in the country, there is no effort done on a context specific formal health technology assessment to make that the chosen interventions are cost-effective.

Thus, it is evident that the high prevalence of the disease in Ethiopia calls for special attentions to patients, demanding action and public health priority from health program managers, planners, policy designer and social workers. In Ethiopia, there are limited research's associated with HRQOL of cancer patients and no research has been conducted to evaluate HRQOL and estimate utility specific to cervical cancer patients. As the only oncology referral hospital, TASH was chosen as the study setting.

1.3. Significance of the study

Considering the increasing prevalence of cervical cancer and its destructive effects on HRQOL and low local reports pertaining to HRQOL of cancer patients, this study aimed to evaluate HRQOL and utility of cervical cancer patients. In addition, it sets out to validate the Amharic version of EORTC QLQ-CX-24, aiming to assess the validity and reliability, which will allow researchers to use validated tool to measure the HRQOL of cervical cancer patients in different study settings in the local community. This study also assessed the predictive factors associated with HRQOL which can be used to guide health care professionals on the treatment protocols and steps to follow as improving HRQOL is a significant end-point in cancer patients. Determining the utility will assist in economic evaluation of treatment alternatives for cervical cancer patients. This will also enable health care providers to make decisions that will improve the Quality Adjusted Life Years (QALY) of patients.

2. Literature review

2.1. Burden of cervical cancer

Cancer is among the non-communicable diseases conditions that have captured the attention of the world. It is a global concern due to its increasing incidence worldwide. The global disease burden study results showed that between 2005- 2015, there was a 33% increase in incidence (GLOBCAN, 2017) and the incidence of cancer is expected to rise to 21.4 million in 2030 (WHO, 2011). In Africa, it is estimated that by the year 2020, Non-communicable disease and cancer will be the leading cause of death. Cancer conditions that once were rare and considered the diseases of western countries, such as colon, breast, and lung cancers, are now frequently diagnosed in less developed countries and their rates are on the rise (American Cancer Society,2014). In 2015, Age standardized incidence rates are the highest in central Sub Saharan Africa 47.4, Southern Sub-Saharan Africa, 46.8 (GLOBCAN,2017).

Ethiopia is among the Sub-Saharan countries with a population size as of July 1, 2017, 94,352, 000 with a female population of 46,987,000 and male population of 47,365, 000 (CSA, 2017). Ethiopia is also among the countries that suffering through the consequences of cancer. Studies show that approximately 60,000-125,000 cancer patients visit the number one hospital in the country, TASH oncology unit annually (TASH, 2018)

Currently, cervical cancer is the second most common cancer among women and the number one cause of death in the country. According to the 2009 WHO report, the age-adjusted incidence rate of cervical cancer in Ethiopia is 26.4 per 100,000 patients from 29.43 million Ethiopian women over the age of 15. It is found that there are 7095 annual number of new cases and 4732 deaths every year (HPV Information Center,2017). Cervical cancer is a fatal disease if not treated or detected early (American cancer society, 2014).

Even though facility-based cancer registries have been set up in five regional university hospitals, since most cervical cancer cases are diagnosed late, the probability for successful treatment is limited and very expensive to pay for. Consequently, the mortality rate is high among the affected patients. At present in Ethiopia, radiotherapy services are only available at TASH (NCCPCIP, 2015). Due to the high incidence of cases the waiting list is long and a patient could wait up to six

to twelve months for treatments as this is the only radiotherapy center in the country. Patients come from everywhere in the county and majority of patients could not afford accommodations in big cities like Addis Ababa (FMOH, 2015).

2.2. Health related quality of life and utility of patients with cervical cancer

As the definition of health by WHO, health is “The state of complete mental and social wellbeing not merely the absence of disease” (WHO, 2008). Quality of Life (QoL) of a person is an indication of a person’s wellbeing in ways of the ability to perform daily task, physical, emotional, cognitive, social, role and sexual functioning. An illness can affect the QoL of a patient in multiple ways and can be stated as a health related quality of life (Fayers and Machin, 2007).

There are five categories to describe health related quality of life. These categories are able to identify the patient’s status normal life; the ability to practically function in a similar manner to healthy individual. As its key elements the quality of life composes of the physical wellbeing of individuals which represents presence or absence of symptoms of bleeding, pain, shortness of breath, fatigue and other physical expressions of illness. Also associated with that functional wellbeing relates to the ability of the patient to undergo simplest tasks independently. Social well-being is the ability to engage in activities with other people (Fayers and Machin, 2007, Greimel *et al.*, 2006). The other element is psychological well-being; this is to measure the presence of depression and anxiety.

Health and quality of life are constantly interlinked elements in patient care. HRQOL is a patient-reported outcome that is usually measured using carefully designed and validated instruments such as questionnaires and interview schedules and core components of the multidimensional HRQOL assessment include physical, functional, psychosocial or emotional and functional or occupational domain (Fayers and Machin D, 2007).

Measuring the health related quality of life of patients will guide health care professionals and policy makers to bring about proper pharmaco-economic interventions. The HRQOL of patients can be measured by using different tools to determine the level of psychometric properties (Ying *et al.*, 2010) studies have shown that in order to properly assess the psychometric properties, combination

of a generic quality of life questionnaire and a specific questionnaire be used (Casper *et al.*, 2017). The EORTC QLQ C30 is a generic module that is validated and reliable to measure the quality of life of cancer patients in Ethiopia (Ayana *et al.*, 2016). The cervical cancer module (EORTC QLQ-CX24) was developed in a multicultural, multidisciplinary setting to supplement the EORTC QLQ-C30 core questionnaire (Greimel *et al.*, 2006).

The utility is an expression of the Quality Adjusted Life Year (QALY) and is commonly used to make evidence-based decision in analysis of cost- effectiveness (Gusi *et al.*, 2010). QALYs are calculated by multiplying the time spent in a health state by the health-state utility values assigned to this health state. Utility values set of a patient will bring several advantages to supplement the understanding of the value of a health state to a person. It will include the time and risk preference for several health state outcomes which could be incorporate into an economic analysis (Whitehead and Ali, 2010).

2.3. Approaches to measuring health related quality of life and utility

There are multiple instruments that measure the QoL of a person. Most of the questionnaires have multiple item questions which could incorporate single global questions that could ask “rate how you have been feeling the past week” and / or group different items in to scales corresponding to different dimensions. The theory of multi-item tests is based on several measurement models that make assumption on the nature of items (Fayers and Machin D, 2007).

One of the models for questionnaires is theory of parallel test, which indicates that items should reflect the level of underlying construct. This theory uses what is known as Likert scales to score items. Factor analysis is used to examine how underlying constructs influence the responses on a number of measured variables. Factor analysis could be used to explore the influence of items on constructs or confirm that items do reflect the construct as predicted. researchers like Kiline (2014) stated that samples for analysis should be in the ratio of participants to variables (2:1) or extracted factors (20:1) and according to Hutcheson and Sofroniou (1999) the sample is sufficient for factor analysis if the number of subjects is between 150- 300. Also, Tabachnick and Fidell (2011)

recommended that in order to obtain a reliable number of estimates through multivariate analysis, the number of observations should be 5-10 times the number of variables in the model.

After development of a questionnaire the reliability and validity of the questionnaire is assured by running several tests, in order to believe the questionnaire is actually measuring what is intended to measure. Content validity; to assure the items are sensible and sufficiently address the domain, construct validity; Examining the theoretical relationship of items to each other and the scales and criterion validity; exploring whether the scale has an empirical association with another external instrument.

There are many instruments used to measure the HRQoL in oncology; Short Form 36 (SF-36) EORTC QLQ-C30, Cancer specific Functional Assessment of Cancer Therapy-General (FACT-G), Cancer specific Visual Analogue Scale-Cancer (VAS-C), Cancer specific Hospital and Anxiety Depression Scale (HADS), Generic Profile of Mood States (POMS), Cancer specific Rotterdam Symptom Checklist (RSCL) (Bottomley., 2002). However, FACT G and the EORTC QLQ 30 Are the most widely used generic cancer instruments while EORTC QLQ CX 24 And FACT-CX are the only cervical cancer specific tools. It is recommended to use the generic tools in conjunction with the cancer specific tools in order to measure the HRQoL of patients.

With the culturally and linguistically diverse global population the use of a valid and reliable instrument is needed to measure subjectively. The European Organization for Research and Treatment of Cancer (EORTC) EORTC QLQC30 is used globally as it is valid to measure QoL in different languages including Amharic. It is designed to be used together with its additional module, specific for patients with cervical cancer – the EORTC QLQ-CX24.

The EORTCQLQ-CX24 does not have a valid Amharic version however it is validated in several European and African countries. A validation study done in the language of isiXhosa and Afrikaans found that is has a good conversion validity, consistency, it is valid and is ready to use for research and clinical use (Du Toit *et al.*, 2015). EORTC QLQ-CX24 was also found to be valid and ready to use in China and Poland (Paradowska *et al.*, 2014, Huang *et al*, 2017). The instrument was found to have a good construct validity, convergent and discriminant validity and criterion

validity which confirms that the items can measure the intended construct in the mentioned languages (Greimel et al.,2008).

2.4. Health related quality of life and utility of patients with cervical cancer

Cervical cancer disrupts the patient's quality of life beginning from the diagnosis stage. With the addition of side effects coming from the treatment options provided to the patient such as surgery, chemotherapy and radiation therapy the impact is multidimensional (Du Toit *et al.*, 2015, Huang *et al.*, 2017). The cost of the treatment and other opportunity costs are also an additional burden to the patient (Pasek, 2005, FMOH, 2015).

The Ethiopian standard treatment guideline also suggests a combination of pharmacological and non-pharmacological treatment strategies for treatment of carcinoma of the cervix. A non-pharmacologic treatment could be surgery, as the main stay treatment, radiotherapy: as treatment or palliation to arrest vaginal bleeding or alleviate pain and a combination of surgery and radiotherapy. As Neo-adjuvant chemotherapy, Cisplatin, 1mg/kg or paclitaxel are given weeks before surgery or radiotherapy. As supplementary treatments Adequate nutrition, and correction of anemia and in advanced terminal cases, provided emotional psychological support (Standard treatment guideline, 2014). The side effects of the treatment modality such as chemotherapy could result in loss of hair, loss of sexual feeling, nausea and vomiting. This is also associated with femininity and sexual identity. Nausea and vomiting are among the treatment side effects most feared by patients undergoing chemotherapy or radiation therapy (Greimel *et al.*, 2008). That it could actually lead to refusal of continuation of treatment (Eran *et al.*, 2015).

These side effects of the treatments are not only just about hair loss and vomiting other bowl complications such as bleeding, perforations and fistulae could also manifest as a result of the treatment. Other urinary complications such as hematuria, vaginal atrophy and agglutination that is also associated with problems in sexual intercourse (Coyne et al., 2008, Jhingran, 2005). From an emotional stability stand point gynecologic malignancies have challenges that can impair the quality of life. Associated with the organ that is affected in these cases the loss of sexual feeling and a result perceived loss of femininity could build a negative emotion (Bradley et al., 2006).

These problems could largely include anger, anxiety, guilt and depression (Wenzel, *et al.*, 2003, Bae and Park,2016). A study conducted in Berlin found that sexual functioning and depression had a negative relationship, to thus in women who have problems with sexual intercourse the depression was higher this, could keep getting worse for months to years since diagnosis (Giovanna, 2013, Nchebe, 2013).

Specifically, from the gynecological cancer patients, those affected by cervical cancer have been reported to show the worst scores in terms of emotional distress and QOL (Distefano, 2009) it was also observed that the vaginal changes will still be reported 2 years after the radiotherapy. Physical and emotional problems, financial problems increased the negative impact on the quality of patients' lives significantly (Pasek, 2005).

A study done on general cancer patients in Ethiopia stated that there was no significant association between the quality of life of patients with cervical cancer and socio-demographic characteristic (Tadele, 2015). However, another study indicates that even though there is no direct relationship, it could be hypothesized that patients experience changes in their marital status after the diagnosis of cervical cancer. the study found that 39% of the patients got divorced during their study period (Khalil *et al.*, 2015).

There is one study done in Ethiopia that indicates the impact of quality of life of cancer patients in general. This study done in TASRH indicated that there is a low-level quality of life with a large number of unmet emotional, financial, pain management and patient care services. It is especially more challenging in Ethiopia as the access to radio and chemotherapy is largely scarce (Tadele, 2015). However, there is no study done assessing the HRQOL of patients specific to cervical cancer.

3. Research questions

This study tried to explore and answer the following questions.

1. Is EORTC QLQ-CX24 locally valid and reliable tool to Ethiopian cervical cancer patients?
2. What is the HRQOL of cervical cancer patients in TASH?
3. What are the predictive factors of the HRQOL of cervical cancer patients in TASH?
4. What is the utility value of cervical cancer patients in TASH?

4. Objectives

4.1. General objective

- To assess Health Related Quality of Life, its associated factors and utility of cervical cancer patients in Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

4.2. Specific objective

- To validate locally translated and culturally adopted version of European Organization for Research and Treatment of Cancer Cervical Cancer Module (EORTC QLQ-CX24)
- To assess the HRQOL of women patients with cervical in TASH
- To estimate the utility value of cervical cancer patients in TASH.
- To identify predictive factors associated with global QOL of cervical cancer patients in TASH.

5. Methods

5.1. Study setting and period

This study was conducted from January to June 2018 in TASH at oncology unit. TASH is a government owned large referral teaching hospital under the administration of Addis Ababa University, located in Addis Ababa, Ethiopia. The hospital has been operating since 1972, currently providing diagnostic and treatment services with 700 beds for about 370,000 to 400,000 patients per year.

The oncology unit of TASH is the only oncology referral unit for the country giving service for over 60,000 patients annually and has both an outpatient and inpatient departments which are currently operating with 6 senior oncologists, 25 residents and 36 oncology nurses and 8 pharmacists (TASH, 2016). Add number of beds

5.2. Study design

A hospital based cross-sectional research design was used to conduct the study. The validation of EORTC QLQ-CX24 module was done as a precondition to using the tool for the evaluation of HRQOL. Following the validation, the HRQOL and utility among cervical cancer patients was assessed.

5.3. Source and study population

All cervical cancer patients being evaluated and treated at the inpatient and outpatient oncology units were included as a source population for the study. The cervical cancer patients, who were evaluated and treated at the units from January to February, 2018 were considered as the study population for the validation of the EORTC QLQ CX 24. And patients, who visited the oncology unit from April to June, 2018 were considered as a study population for the HRQOL assessment. Patients had to meet the eligibility criteria and provide an informed consent to participate in the study.

5.4. Inclusion and exclusion criteria

Patients with pathological diagnosis of cervical cancer and aged 18 years and older were considered eligible. Patients who are critically ill (too weak to communicate, according to the oncology physician) or have a psychiatric disorder were excluded from the study.

5.5. Sampling

5.5.1. Sample size determination

The sample size for the validation was calculated by adopting the Hutcheson and Sofroniou (1999) recommendation of 150 as a minimum sample size sufficient for validation of instruments and 171 patient's data was collected up to the end of the data collection period.

For the HRQOL and utility study, the sample size was calculated by using single population proportion formula (Fisher et al.,1983). There are no studies conducted evaluating the HRQOL and utility of cervical cancer patients thus desired proportion of 50% was used in order to obtain the maximum sample size.

$$n = \frac{\left(z \frac{\alpha}{2}\right)^2 p(1-p)}{d^2}$$
$$n = \frac{(1.96)^2(0.5)(0.5)}{(0.05)^2} = 384$$

Adding 5% contingency= 404

Where: **n**= sample size desired

Z α /2 = 1.96 (Z=score corresponds to 95% confidence level \pm CI)

P= proportion of patients with above average health related quality of life

d2 = margin of error (0.05)

Adding 5% contingency for possible inappropriate and no responses, a total of 404 cervical cancer patient were approached.

5.5.2. Sampling technique

All cervical cancer patients being evaluated and treated at the inpatient and outpatient oncology units, during the study periods, who meet the eligibility criteria were approached and from those willing to participate in the study data were included. Due to limited number of patients in the study period, participants were recruited consecutively until the required sample size was reached.

5.6. Study variables

5.6.1. Dependent variables

- Global quality of life
- Functional and symptom variables

5.6.2. Independent variables

- Socio demographic and socio-economic characteristics such as age, marital status, , educational status, and average monthly household income
- Medical characteristics such as medical service status, presence of other disease, time since diagnosis, current cancer stage and current type of anticancer treatment
- The functional and symptom variables are considered independent in the multivariable analysis against GQOL.

5.7. Data collection instruments

An Amharic version of EORTC-QLQ-C30, EORTC-QLQ- Cx24, EQ 5D-5L and EQ-VAS were adopted and included in the study with the approval of the EORTC and Euro QoI Research Foundations.

A questionnaire was developed to collect the socio-demographic, socio-economic and medical characteristics of patients. The questionnaire included questions about age, marital status, and level of education, occupation and average monthly household income. In addition, data on medical characteristics of patients through chart review (patient status, time since diagnosis, stage of

cancer, current type of anticancer treatment and comorbid conditions) were filled through chart review by data collectors.

EORTC-QLQ-C30

EORTC QLQC-30 a globally used and validated Amharic generic questionnaire was used to assess the HRQOL of patients. It contains a total of 30 questions measuring five functional scales (Physical, Role, Emotional, Cognitive and Social), nine symptom scales (Fatigue, Nausea and vomiting, Pain, Dyspnea, Insomnia, Loss of appetite, Constipation, Diarrhea and Financial difficulties) and global health status scale. Each item was scored 1 (“not at all”) to 4 (“very much”) with the exception of the global health status and global QoL which were scored 1 (“Extremely poor”) to 7 (“Best”) (Fayers *et al.*, 2008).

EORTC-QLQ- CX24

EORTC-QLQ- CX24 is a cervical cancer specific module that contains 24 questions used to assess the HRQOL of patients. It contains four functional scales (body Image, sexual activity, sexual enjoyment and sexual/vaginal functioning) and five symptom scales (symptom experience, menopausal symptoms, peripheral neuropathy, lymphadenoma and sexual worry). All of the questions use four-point Likert scale. Scores range from 0 to 100, with higher scores indicating better functioning and better state of health (Fayers *et al.*, 2008). Since the questionnaire did not have a validated Amharic version, it was validated prior to the assessment of HRQOL of the patients. The pilot test was done with a selected number of cervical cancer patients. They were asked to fill in the questionnaire under observation of a researcher or interviewed based on their preference and comment on content, layout, volume and simplicity. Depending on the result of the pilot test, correction and modification was made by rephrasing sexually sensitive items of questionnaire before actual data collection on the study population started

EQ 5D 5L and EQ VAS

The generic EQ-5D-5L questionnaire uses five question categories using a five-point scale (“Not at all” to “extreme”) in order determine the state of HRQOL though five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-VAS scale uses a

numeric range that will go from 0 (worst) up to a 100 (best) in a 20 cm ruler for the patient to mark his or her current status (Gusi *et al.*, 2010).

Eastern Cooperative Oncology Group Performance Status (ECOG-PS): It was used to establish patients' performance status, it is commonly used to identify how the disease affects the patient's ability to perform activities of daily living, and to determine appropriate treatment and prognosis. The ECOG-PS scale is rated from (0 fully active to 5 death) where groups of rank 0-1 are classified as good status and 2-4 as bad (Conill *et al*,1990). ECOG-PS was used for the known group validation of EORTC QLQ CX 24.

5.8. Data quality management

To maintain the quality of the data, structured and validated English version of the EORTC QLQ CX-24 questionnaires were adopted and developed through forward backward translation to Amharic. The translated version of the questioner was pilot tested and data was collected for the validation.

The validated Amharic versions of EORTC QLQ-C30, EORTC QLQ-CX24, EQ-5D and EQ-VAS were used to collect the data. Two oncology nurses with the qualification of BSc were recruited as data collectors. one day training was given focusing on; purpose of the study, contents of the questionnaire, identification of patients based on the inclusion/exclusion criteria, how to approach and get consent from patient. All collected data were checked for completeness by the principal investigator in the daily supervisions and reliability and validity was done by using SPSS 23.0

5.9. Data Scoring

EORTC QLQ C-30 and EORTC QLQ-CX24

The collected responses were coded, entered and cleaned. The raw scores for both EORTC QLQ C-30 and EORTC QLQ-CX24 were computed to scores ranging from 0 to 100, with higher scores indicating better functioning and better state of health.

The scoring of the QOL of the patients was based on the scoring manual provided by the quality of life coordinator at the European Quality OF Life Data Center. Linear transformation to 0-100

to obtain the score S, was done by using the formula below (Aaronson, 1993). Items representing one sub-scale were coded in to their respective multi-item scales.

- Functional scales for EORTC QLQ- C30; Physical functioning (questions no: 1-5), emotional functioning (questions no: 21-24), cognitive functioning (question no: 20&25) and social functioning (questions no: 26&27).
- Symptom scales EORTC QLQ-C30: Fatigue (questions no;10,12&18), Nausea and vomiting (questions no: 14&15), Pain (questions no;9&19), dyspnea (questions; 8), insomnia (question no :11), and loss of appetite (questions 13), constipation (questions no: 16), diarrhea (questions no: 17) and financial difficulty (questions no: 28).
- Functional scales for EORTC QLQ-CX24: body image (questions;45-47), sexual activity (question no:11), sexual enjoyment (question no: 54) and sexual/vaginal functioning
- Symptom scales for EORTC QLQCX24: Symptom experience (questions no; 31-37,39, 41-43), lymphadenoma (question no:38), peripheral neuropathy (question no:40), menopausal symptoms (question no:44) and sexual worry (question no:48)

Raw score

Calculate the raw score

$$\text{Raw Score} = \text{RS} = (I_1 + I_2 + \dots + I_n) / n$$

Linear transformation

Linear transformation to 0-100 to obtain the score S,

$$\text{Functional scales: } S = \{1 - (\text{RS} - 1)\} * 100$$

Range

$$\text{Symptom scales / items: } S = \{(\text{RS} - 1) / \text{range}\} * 100$$

$$\text{Global health status / QOL: } S = \{(\text{RS} - 1) / \text{range}\} * 100$$

Range is the difference between the maximum possible value of RS and the minimum possible value. The EORTC QLQ-C30 and EORTC QLQ-CX24 were designed so that all items in any scale take the same range of values; Most items are scored 1 to 4, (Range = 3). The exceptions were the items contributing to the global health status / QOL, which are 7-point questions with range of 6. Therefore, the range of RS equals the range of the item values. High mean scores represent better functioning in the functioning scales and global health status, but a high level of difficulty for symptom scales and single symptom items (Aaronson, 1993).

Since there were no hard scoring guides of the EORTC QLQ-C30 and EORTC QLQ-CX24 that translate to mean significant impairment. After computing, the domains were dichotomized to “affected” and “not affected”. The score below 75 was taken for an affected functional and GQoL scales while above 25 were taken as an affected symptom scale.

EQ 5D- 5L and EQ VAS

In terms of the EQ 5D- 5L and EQ VAS, the instrument measures the utility. This score is known as the utility score. Utility score was obtained from the possible 3125 health states defined by the 5 dimensions and disutility coefficient of the general population (Welie et al., 2018)

5.10. Method of Data Analysis and interpretation

Data were entered into the Statistical Package for Social Sciences (SPSS) version 22.0 for analysis of the survey results (SPSS, Inc. Chicago, USA). Before analyzing the surveys, responses were reverse coded as appropriate for some scales; sexual enjoyment and sexual activity. Descriptive statistics (frequency, percentage, mean, SD) were used to report demographic and clinical characteristics.

Analysis and interpretation for the validation of EORTC QLQ-CX24

Psychometric properties of the EORTC QLQ-CX 24 were assessed in terms of acceptability, internal consistency, construct validity, concurrent validity and known group validity.

The acceptability of the EORTC QLQ-CX 24 was assessed in term of response rate, percentage of missing data, time needed to complete the questionnaire and details of items considered upsetting, confusing or difficult in the questionnaire to respond.

The reliability was assessed by measuring the internal consistency of EORTCQLQ-CX24 using Cronbach’s α coefficient for each domain where $\alpha \geq 0.7$ indicated adequate scale reliability of the tool (Cronbach, 1951). The coefficient ranges from 0 to 1, as the values get higher it indicates a better reliability.

The scale structure was evaluated by multi-trait scaling analysis. This analysis was based on an evaluation of item-scale correlations for item-convergence and item-discriminance. Evidence of item-convergence was defined as a correlation of ≥ 0.40 between an item and its own scale. A lower correlation of an item with scales other than its own in comparison to the correlation with its own scale was evidence for item-discriminance (Fayers and Machin, 2007; Hua ,*et al.* 2013). The convergent, discriminate and concurrent validity (with EORTC QLQ-C30) for each scale was evaluated by assessing the Pearson's correlation coefficient. EORTC QLQ-C30 and the EORTC QLQ-CX24, this correlation aimed to assess if and to what extent clinical overlapping existed between the EORTC QLQ-C30 and the EORTC QLQ-CX24 scales

Scaling errors were defined as cases in which an item correlated “significantly less” with its own scale than with other scales. Known group validity between FIGO stages, treatment and ECOG - PS of patients was analyzed by independent t-test (Beaton *et al.*, 2000). The significance level was set using the two-tailed test at p -value <0.05 .

Analysis and interpretation for the assessment of HRQOL and Utility

Mean scores and mean differences of EORTC- QLQ-C30 and EORTC- QLQ-C24 were calculated. After HRQOL, symptom and functional scales were dichotomized, and One-way ANOVA was employed to determine the mean difference between variables, $P<0.05$ were considered as significant. A non- parametric test (Mann- Whitney U test & Kruskal-wallis test) was done to assess the variable that don't have a normal distribution. A forward stepwise multivariate logistic regression analyses were used to explore the associations with GQOL. Variables with $p<0.25$ on the binary logistic regression were considered as the independent variables for the multivariable analysis.

Analysis and interpretation for the utility score

Microsoft excel was used for the analysis of EQ 5D-5L. The coefficients and level specific utility values obtained from a hybrid regression model for Ethiopian population (Welie et al., 2018) were used to compute the values of each state.

$$\text{Utility value} = \text{mo2} * \text{coef1+} + \text{mo3} * \text{coef2+} + \text{mo4} * \text{coef3+} + \text{mo5} * \text{coef4+} + \text{sc2} * \text{coef5+} + \text{sc3} * \text{coef6+} + \text{sc4} * \text{coef7+} + \text{sc5} * \text{coef8+} + \text{ua2} * \text{coef9+} + \text{ua3} * \text{coef10+} + \text{ua4} * \text{coef11+} + \text{ua5} * \text{coef12+} + \text{pd2} * \text{coef13+} + \text{pd3} * \text{coef14+} + \text{pd4} * \text{coef15+} + \text{pd5} * \text{coef16+} + \text{ad2} * \text{coef17+} + \text{ad3} * \text{coef18+} + \text{ad4} *$$

mo=motility, sc=self-care, ua=usual activity, pd=pain and discomfort, ad=Anxiety and depression

5.11.Ethical considerations

Ethical clearance was obtained from the Ethics Review Committee of the School of Pharmacy, Collage of Health Sciences; Addis Ababa University (Ref. No.: *ERB/SOP/07/10/2018*) Permission was received from EORTC research group to use the questionnaires. Participants were informed about the objective of the study before data collection, asked for their verbal consent before participating in the study, privacy and confidentiality were maintained by omitting personal identifiers throughout the study.

5.12.Operational definitions

Functional scales: physical, emotional, role, cognitive, social, sexual functioning, future perspective, body image, and sexual enjoyment.

Symptom scales; fatigue, nausea/vomiting and pain, dyspnea, insomnia, appetite loss, constipation, diarrhea and financial difficulties, Symptom experience, lymphadenoma, peripheral neuropathy, menopausal symptoms and sexual worry.

Affected functional and symptom scales: Scoring for functional scales < 75% and > 25% for symptom scales.

Affected Global health status/QoL: Scoring < 75% or below the cut of point of (75).

6. Results

6.1. Results for validation of EORTC QLQ-CX24

6.1.1. Socio-demographic and clinical characteristics of study participants

One hundred seventy-one cervical cancer patients completed the questionnaires and included in the data analysis, with mean age of 52.15 ± 10.4 years. All patients responded to both the EORTC QLQ-C30 and the EORTC QLQ-CX24 without missing an item. Majority 118 (69%) of the patients had no formal education and 95(56%) of the patients were married. Although majority 165(97%) of the patients diagnosed at FIGO stage of II-IV, approximately 145 (85%) of the patients had good performance status (ECOG-PS). Among the participants, 158(92.4%) of them are as outpatients. More than half 88(51%) of the patients were receiving no treatment while 76 (44%) of them were receiving radiotherapy as primary treatment modalities (Table 1).

Table 1: Socio-demographic and clinical characteristics of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	Number of patients (%)
Age category	
25-54	98(57.3%)
55-64	49(28.7%)
>65	24(14%)
Religion	
Orthodox	112 (65.5%)
Protestant	35 (20.5%)
Muslim	24 (14.0%)
Marital Status	
Single	2 (1.2)
Married	96 (56.1%)
Divorced	30 (17.5%)
Widowed	43 (25.1%)
Educational Status	

Unable to read and write	128(58.5%)	SD=
Informal education	28(16.3%)	
Primary education	22(12.9%)	
Secondary Education	14(8.2%)	

FIGO

Stage 1	6 (3.5%)
Stage 2	57 (33.3%)
Stage 3	49 (28.7%)
Stage 4	59 (34.5%)

Current treatment

Surgery	2 (1.2%)
Chemotherapy	5 (2.9%)
Radiotherapy	76 (44.4%)
No treatment	88 (51.5%)

ECOG-PS

Good	145 (84.8%)
Bad	26(15.2%)

Standard deviation; FIGO= International Federation Gynecology and Obstetrics
 ECOG-PS= European Cooperative Oncology Group Performance Status; n= Sample size

6.1.2. Reliability and validity of EORTC QLQ-CX24

Acceptability

The EORTC QLQ-C30 and EORTC QLQ-CX24 were easily understood with full compliance. None of the patients refused to participate and no missing responses. The total time for completion of the questionnaires was approximately 10-12 min with assistance and 15-20 min without assistance. Most patients reported all questions to be clear and easy to understand even with those who have no formal education.

Reliability and validity

Results of multi-trait scaling analyses are presented in Table 2. Reliability of the tool, measured by internal consistency, determines the tool reproducibility or consistence. All of the items had

Cronbach alpha of $\alpha \geq 0.70$. Inter item constancy results indicated that all of the items of EORTC QLQ-CX24 had a strong consistency. In terms of convergent validity, all items showed a good correlation with their own scales ($r \geq 0.4$). In another extreme, the item discriminance, Items correlated higher with their own scale than with the other scales, confirming that unrelated items should have a lower correlation was also evaluated. There were no scaling errors found on the item-discriminance analysis.

Table 2: Multi-trait scaling analysis between scale items on the EORTC QLQ-CX24 of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

EORTC QLQ-CX24	Item/s Number	Mean \pm SD	Cronbach alpha	Convergent validity*	Discriminant Validity†
Symptom scales					
Symptom experience	31-37,39,41-43	42.97 (23.68)	.837	.504-.768, 100%	.004-.627
Body image	45-47	45.22 (39.57)	.963	.951-.974,100%	.16-.647
Sexual/Vaginal function	50-53	64.47 (28.84)	0.7	.622-.880,100%	.017-.789
Symptom items					
Lymphedema	38	12.86 (27.83)	N/A	N/A	.06-.329
Peripheral neuropathy	40	40.54 (39.02)	N/A	N/A	.046-.494
Menopausal symptoms	44	54.77 (37.50)	N/A	N/A	.006-494
Sexual worry	48	33.52 (46.23)	N/A	N/A	0.098-.700
Functional Items					
Sexual activity	49	92.98 (22.63)	N/A	N/A	0.20-0.392
Sexual enjoyment	54	61.40 (31.93)	N/A	N/A	0.06-0.39

SD, standard deviation; N/A, not applicable; *Item-own scale correlation, Pearson correlation coefficient; †Item-other scale correlation, Pearson correlation coefficient.

Concurrent validity was performed to show the relationship of items and scales of EORTC QLQ-CX24 with another established questionnaire EORTC QLQ-C30, to confirm measurement efficacy of the measurement tool. Scales and items of the EORTC QLQ-CX24 were found to be correlated, to some extent, with the scales of the EORTC QLQ-C30 (Table 3). This indicated that the EORTC

QLQ-CX24 partially assessed a unique set of HRQOL domains that are currently not covered by the core questionnaire. The symptom experience, body image, peripheral neuropathy and menopausal symptoms scales correlated strongly with the EORTC QLQ-C30 functioning scales ($r \geq 0.40$). The symptom scale of EORTC QLQ-CX24 correlated strongly with all subscale of the EORTC QLQ-C30 except for diarrhea and financial impact. The menopausal symptoms scale indicated a strong negative correlation with the physical functioning, emotional functioning and social functioning. On the other hand, scales that were related to sexuality (the sexual/vaginal functioning, sexual worry, and sexual enjoyment scales) correlated weakly with the EORTC QLQ-C30.

Known group validity was established by assessing the ability of EORTC QLQ-CX24 to detect difference in level of HRQOL across patients performance status, FIGO classification and whether patients being on treatments or not (Table 4). Results showed that, symptom experience and sexual/vaginal functioning scales was capable of discriminating among patients with different FIGO stages ($p=0.03$). No significant difference of scores for patients with different FIGO stages was found in other functioning and symptoms scales of the EORTC QLQ-CX24 ($p= 0.68$). The functioning and symptom scales did not result in a significant difference among the ECOG-PS of patients except for lymphadenoma ($p=0.02$).

The sexual vaginal functioning mean score showed a difference among treatment groups. Although not significant, difference was observed between the groups and other scales. Scores of the symptom functioning, peripheral neuropathy, menopausal symptom and sexual worry scales for patients with progressive cervical cancer were higher than for those with early cervical cancer, this indicates that as the stage progresses the symptoms progress as well. On the other hand, the result for sexual enjoyment and sexual activity are reversed as the stage progresses, the results get lower

Table 3: Pearson correlation between EORTC QLQ-CX24 and QLQ C-30 of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

EORTC QLQ C-30	EORTC QLQ CX-24								
	SE	BI	S/VF	LA	PN	MS	SW	SA	SE
Functioning scales									
Physical	-.560**	.418**	.369	-.203**	.421**	-.428**	-.141	.129	.102
Role	-.486**	.419**	.071	-.124	.401**	-.351**	-.145	.069	.175
Emotional	-.454**	.493**	.313	-.139	.314**	-.403**	-.142	.211**	-.034
Cognitive	-.334**	.350**	.172	-.292**	.249**	-.202**	-.146	.082	.078
Social	-.481**	.463**	.426	-.109	.389**	-.432**	-.083	-.006	-.187
Symptom scales									
Fatigue	.583**	.355**	-.015	.140	.305**	.342**	.093	-.057	-.143
Nausea and Vomiting	.312**	-.148	-.282	.020	.177*	.176*	.109	-.064	-.111
Pain	.635**	.320**	-.201	.131	.383**	.416**	.015	-.017	-.148
Dyspnea	.500**	.230**	-.282	.195*	.174*	.289**	.040	-.040	.099
Insomnia	.397**	.264**	.184	.067	.223**	.226**	.047	-.035	-.148
Loss of appetite	.454**	.205**	.001	.062	.336**	.280**	-.009	.034	-.489*
Constipation	.650**	.326**	-.245	.125	.231**	.301**	.092	-.053	.174
Diarrhea	.074	-.042	-.562*	.109	.184*	-.011	-.037	-.073	.391
Financial difficulties	.188*	.289**	.032	.154*	.203**	.214**	.104	.089	.120
GQOL	-.636**	.396**	.525*	-.141	.326**	-.345**	-.057	-.014	-.273

*Significant on p< 0.01 level, ** Significant on p< 0.05 level, SE=Symptom experience, BI=Body image, S/VF=Sexual/Vaginal functioning, LA=Lymphadenoma, PN=Peripheral Neuropathy

MS=Menopausal symptoms, , SA=Sexual activity, SW=Sexual worry, SE=Sexual enjoyment

Table 4: Known group comparisons of EORTC QLQ-CX24 of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

EORTC QLQ-CX24	ECOG-PS		FIGO stages		Treatment group	
	Good PS (0-1)	Poor PS (2-4)	Stage I	Stage II-IV	On treatment	Off treatment
Symptom experience	42.40 (24.40)	46.15 (19.22)	16.16 (12.37)*	43.94(23.44)*	40.67 (25.46)	45.14 (21.78)
Body image	46.89 (39.35)	35.89 (40.28)	61.11(44.30)	44.64(39.42)	47.25 (39.02)	43.30 (40.22)
Sexual /vaginal functioning	63.88 (29.56)	75.00 (0.00)	83.33(11.78)*	62.25 (29.62)*	54.62 (33.87)*	73.33 (21.44)*
Lymphedema	10.57 (24.75)*	25.64 (39.22)*	5.55 (13.60)	13.13(28.20)	16.86 (32.24)	9.09 (22.4)
Peripheral neuropathy	40.22 (39.06)	42.30 (39.50)	38.88 (25.09)	40.60 (39.48)	44.97 (39.79)	36.36 (38.0)
Menopausal symptoms	53.79 (37.92)	60.25 (35.30)	50.00 (45.94)	54.94 (37.32)	53.81 (37.83)	55.68 (37.38)
Sexual worry	32.41 (46.13)	39.74 (47.15)	27.77 (49.06)	33.73 (46.26)	32.53 (44.77)	34.46 (47.79)
Sexual activity	92.18 (23.89)	97.43 (13.07)	94.44 (25.09)	92.92 (22.62)	92.36 (24.59)	93.56 (20.75)
Sexual enjoyment	62.96 (32.11)	33.33(0.00)	66.66 (0.000)	60.78 (33.81)	59.25 (32.39)	63.33 (33.14)

*Significant (P<0.5)

6.1.3. Summary

Over all the results of the validation study indicate that the EORTC QLQ CX-24 module has a good internal consistency with all items resulting in Cronbach's alpha value > 0.7 . The results of the convergent and discriminant validity were indicative of the ability of items to reflect on their respective domains and the ability to differentiate from the other domains. On the criterion validity the instrument was able to differentiate between ECOG-PS and FIGO stages to some level.

In conclusion, the Amharic version of the EORTC QOQ CX 24 was proved to be patient-friendly and well accepted by patients with cervical cancer with a high completion rate and a low missing response rate of items. Finding of this study provide that the Amharic version of the EORTC QLQ-CX24 questionnaire can be used as acceptable, a reliable and efficient tool in clinical use and clinical research to study the HRQoL of cervical cancer in Ethiopia.

6.2. Results for HRQOL and Utility of cancer patients

6.2.1. Socio-demographic, socio-economic and clinical characteristics of the study participants

A total of 404 patients participated in the HRQOL study. The mean age was found to be 52.09 ± 0.50 years; ranged from 28– 83 years. Majority (56.9%) of the participants were in the age category of 25-54 years and 210 (52.0%) of the participant were married. About two-third (65.3%) of the patient were Orthodox Christians; and almost half (45.3%) of the participants came from the Oromia region. The educational background of the patients indicated that the majority (69.6%) of the participants had no formal education. Housewives 164(40.6%) and Farmers 144 (35.6%) led the category of occupation of participants. The average monthly household income for the majority (43.8%) of the participants was below poverty line, an income of less than 600 birr (Table 5).

Table 5: Socio-demographic and Socio-economic characteristics of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	(%)
1.1. Age (in years)	
25-54	230(56.9%)

55-64	120(29.70%)
>65	54(13.3%)
1.2. Region	
Oromia	183(45.3%)
Amhara	102(25.2%)
Addis Ababa	62(15.3%)
SNNPR	42(10.4%)
Others ^{a*}	15(3.7%)
1.3. Religion	
Orthodox	264(65.3%)
Protestant	78(19.3%)
Muslim	54(13.4 %)
Other*	2(0.5%)
1.4. Marital status	
Single	5(1.2%)
Married	210(52.0%)
Divorced	69(17.1%)
Widowed	117(29.0%)
1.5. Educational background	
Unable to read and write	281(69.6%)
Informal education	28(6.9%)
Primary education	42(10.4%)
Secondary education	37(9.2%)
Higher education	16(4%)
1.6. Region	
Oromia	183(45.3%)
Amhara	102(25.2%)
Addis Ababa	62(15.3%)
SNNPR	42(10.4%)

Others ^{a*}	15(3.7%)
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1.7. Occupation

Government employee	23(5.7%)
Private	10(2.5%)
Merchant	41(10.1%)
Retired	9(2.2%)
Farmer	144(35.6%)
Housewife	164(40.6%)
Others ^{b*}	13(3.2%)

1.8. Average household income (ETB)

<600	177(43.8%)
>600	217(53.7%)

Others^{b*} = Housemaids, commercial sex workers, Beggars, Others^{a*} Tigray, Direedawa, Harar

Participants visiting the out-patient department 378 (93.8%) and those on a follow up schedule 329 (81.4%) were majority in the study. Patients diagnosed with FIGO stage IV cervical cancer constituted the highest proportion (35.6%) of participants. Majority (64.6%) of the participants were diagnosed within less than one year of the data collection period. The leading (54.2%) were not receiving any cancer treatment during the study period and 131(32%) have not received treatment in the past either. From those who have taken cancer treatment, most (38.9%) of them were on radiotherapy. The majority 345(85.4%) of the patients did not have comorbid conditions. Of those who had comorbid conditions, highest (5.0% & 5.9%) were registered on the charts of having hypertension and HIV (Table 6).

Table 6: Clinical characteristics of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	(%)
2.1. Admission status	
New Admission	75(18.6%)
Follow up	329(81.4%)
2.2. Patient care type	
Inpatient	25(6.2%)

Out patient	378(93.8%)
2.3. FIGO Stages	
Unknown	11(2.70%)
Stage I	10(2.50%)
Stage II	132(31.90%)
Stage III	108(26.70%)
Stage IV	144(35.60%)
2.4. Time since diagnosis	
<12 months	261(64.6%)
1-5 years	130(32.2)
5 years and above	12(3.0%)
2.5. Current treatment	
Surgery	9(2.2%)
Chemotherapy	19(4.7%)
Radiotherapy	157(38.9%)
No treatment	219(54.2%)
2.6. Comorbid conditions	
None	345(85.4%)
Hypertension	20(5.0%)
HIV	28(6.9%)
Diabetes	4(1.0%)
Chronic Kidney Disease	3(0.7%)
Anemia	2(0.5%)
Peptic Ulcer Disease	1(0.2%)
2.7. Past treatment history	
None	133(32%)
Surgery	15(3.7%)
Chemotherapy	16(4.0%)
Radiotherapy	171(42.3%)

Surgery and chemotherapy	10(2.5%)
Chemotherapy and Radiotherapy	38(9.4%)
Surgery, Chemotherapy and Radiotherapy	21(5.2%)

6.2.2. Global quality of life and utility among cervical cancer patients

The global health status/QOL mean score was found to be 48.3 ± 23.77 . The EORTC QLQ-C30 multiple and single item scales were also evaluated and the functional scales ranged from 40.38 ± 30.93 to 79.8 ± 26.12 with the least being social functioning and highest cognitive function. For the symptom scales, the financial difficulty had the highest mean of 68.89 ± 35.42 and with the exception of diarrhea 7.43 ± 21.73 and nausea and vomiting 21.7 ± 30.12 , all the other items indicated moderate to high symptoms. The EORTC QLQ-CX24 items exhibited a range of mean scores from 6.12 ± 19.70 for the sexual activity to 64.56 ± 29.75 sexual and vaginal functioning. On the symptom scales the least score was on Lymphadenoma 12.76 ± 27.7 and highest was for Menopausal symptoms 55.77 ± 35.64 (Table 6).

Table 7: Mean, Standard Deviation and Cronbach's alpha values of EORTC QLQ-C30 and EORTC QLQ-CX24 of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

	EORTC QLQ- C30	Item Numbers	Mean \pm SD	Cronbach's Alpha
EORTC QLQ C 30	Global QoL	29, 30	48.3 ± 23.77	0.93
	Functional scales			
	Physical functioning	1-5	53.0 ± 26.05	0.89
	Role functioning	6,7	47.15 ± 34.05	0.93
	Emotional functioning	21-24	57.13 ± 34.50	0.94
	Cognitive Functioning	20,25	79.8 ± 26.12	0.64
	Social functioning	26,27	40.38 ± 30.93	0.85
	Symptom scale			
	Fatigue	10,12,18	57.2 ± 28.1	0.83
	Nausea and Vomiting	14,15	21.7 ± 30.12	0.79

	Pain	9,19	59±30.07	0.75
	Dyspnea	8	30.8±32.10	N/A
	Insomnia	11	46.69±39.25	N/A
	Loss of appetite	13	54.45±39.28	N/A
	Constipation	16	53.96±40.78	N/A
	Diarrhea	17	7.43±21.73*	N/A
	Financial difficulty	28	68.89±35.42	N/A
EORTC QLQ-CX24				
EORTC QLQ-CX24	EORTC QLQ CX-24	Item Number	Mean±SD	Cronbach's' Alpha
	Body image	45-47	50.27±38.76	0.92
	Sexual activity	49	6.12±19.70*	N/A
	Sexual enjoyment	54	44.7±30.37	N/A
	Sexual/Vaginal functioning	50-53	64.56±29.75	0.79
	Symptom scales			
	Symptom experience	31-37,38,41-43	42.59±22.5	0.74
	Lymphadenoma	38	12.76±27.7	N/A
	Peripheral neuropathy	40	42.39±39.27	N/A
	Menopausal symptom	44	55.77±35.64	N/A
Sexual worry	48	55.77±35.64	N/A	
*non-normal distribution				

The EQ 5D visual scale analog resulted in a score of 65.7±20.83. And the utility value set was found to be 0.77. From the five dimensions of the EQ 5D, highest percentage (36.1%) were able to walk and move without a problem; while the highest (32.4%) complaint was that they had a slight problem moving around and 6(1.5%) were unable to move without help. On the self-care dimension; the majority (77.5%) had no problem taking care of themselves and the least (0.5%) of the participants had extreme inability to take care of themselves. The pain dimension showed that the highest percentage (36.9%) of the participants had a slight feeling of being unwell and (16.3%)

had severe pain. The majority of the participants 160 (39.6%) and 144 (35.6%) reported no problem and slight problems of anxiety and depression (Figure 2).

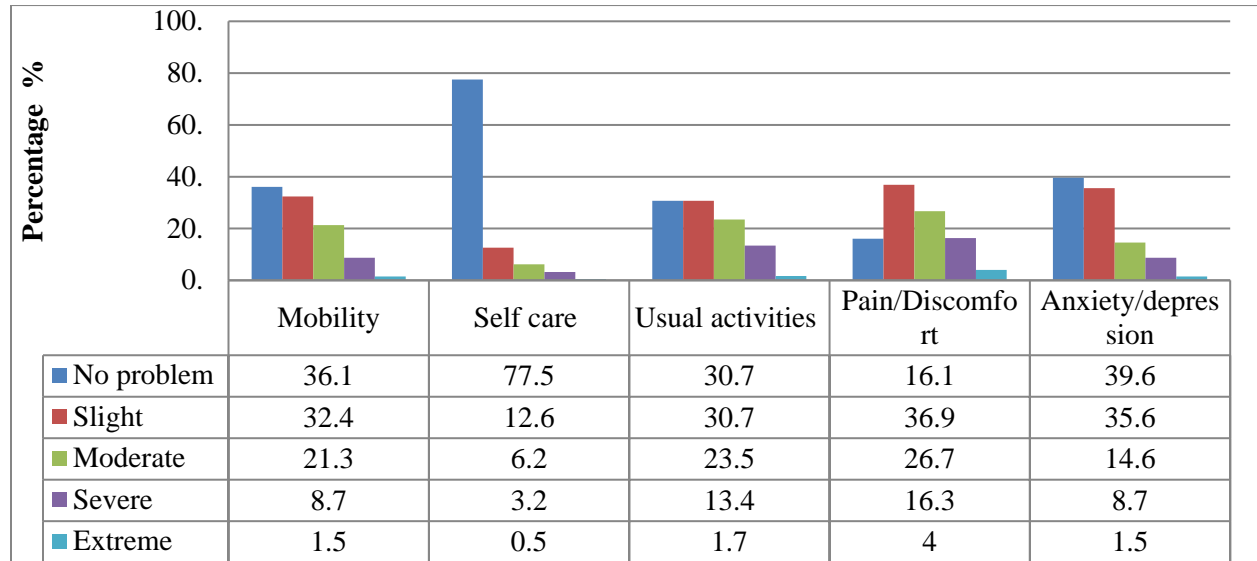


Figure 1: EQ 5D-5L, percentage of patient reported results of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

6.2.3. Mean difference of EORTC QLQ-C30 and EORTC QLQ-CX 24 scales with socio-demographic and clinical characteristics

EORTC QLQ-C30

Mean differences of EORTC QLQ-C30 functional scales with socio-demographic, Socio-economic and clinical characteristics

There was no significant mean difference across age, marital status and average monthly household income categories on the functional scales. Educational status showed significant mean difference on all functional scales except physical and cognitive functioning (Table 9).

Table 8: Mean differences in EORTC QLQ-C30 functional scales of patients with cervical cancer with socio-demographic characteristics at TASH, Addis Ababa, Ethiopia, 2018.

Variables	GQOL	PF	RF	EF	CF	SF
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Age

Category						
25-54	47.97±23.17	52.28±26.42	45.07±34.37	56.41±33.97	79.85±26.1	38.11±30.81
55-64	48.68±23.88	52.33±25.74	48.33±34.19	58.68±35.11	80.41±25.71	42.77±30.38
>65	49.53±26.37	57.53±28.52	53.39±35.37	56.79±36.30	78.7±27.55	44.75±32.34
<i>p-value</i>	0.89	0.40	0.25	0.84	0.82	0.22
Marital status						
Single	70.0±18.25	65.33±25.99	80±21.73	66.66±33.33	83.33±23.57	53.33±44.72
Married	49.04±23.18	53.68±25.39	48.57±34.4	55.99±34.59	80.79±25.44	38.01±30.02
Divorced	46.25±21.46	53.43±27.26	42.75±32.27	61.11±31.30	79.46±26.68	38.4±25.77
Widowed	47.72±26.22	50.88±28.34	45.58±36.11	55.84±36.62	78.2±27.37	45.15±33.97
<i>p-value</i>	0.17	0.57	0.10	0.64	0.84	0.15
Educational status						
Unable to read and write	44.6±23.33	50.84±26.43	43.95±33.67	53.32±35.52	77.69±27.22	35.88±28.73
Informal education	53.57±24.88	55.95±25.68	45.83±33.83	63.39±31.86	88.09±18.06	41.66±35.28
Primary education	54.16±22.56	58.25±25.96	53.17±33.58	61.7±31.88	81.34±24.74	53.57±33.64
Secondary education	58.78±18.73	57.29±27.05	54.5±36.14	73.64±25.34	87.83±21.74	51.35±31.02
Higher education	66.66±25.27	62.08±27.18	72.91±36.95	63.02±35.61	81.25±27.13	57.29±34.4
<i>p-value</i>	0.00*	0.15	0.01*	0.01*	0.79	0.00*
Occupation						
Government employee	64.13±21.53	70.72±24.26	71.73±30.33	70.65±31.96	88.40±16.99	60.86±36.44
Private	60±21.44	51.33±20.13	51.66±39.63	66.66±21.15	80±30.22	51.66±37.22
Merchant	49.39±25.09	56.09±30.07	48.78±36.20	56.50±37.15	84.55±22.48	50±30.27
Retired	58.33±32.27	77.03±16.36	96.29±7.34	77.77±22.43	88.88±18.63	77.77±25.00
Farmer	45.25±20.11	50.50±23.67	41.78±29.43	54.28±34.01	77.54±26.75	30.78±23.84

Housewife	47.81±25.22	50.69±27.24	45.63±36.02	57.52±35.76	78.96±27.68	41.26±32.68
Other	43.58±26.82	53.33±32.31	39.74±35.70	40.38±25.65	80.76±22.40	34.61±22.00
<i>p-value</i>	0.08	0.02*	0.00*	0.07	0.40	0.00*
Average monthly household income (ETB)						
<600	46.79±24.95	52.35±26.42	44.91±34.53	54.80±35.54	77.96±26.78	39.07±31.48
>600	50.15±22.72	53.85±26.33	49.23±34.31	59.56±33.46	81.72±25.12	41.02±30.68
<i>p-value</i>	0.16	0.57	0.22	0.17	0.15	0.36

PF=Physical functioning, EF=Emotional functioning, RF=Role functioning, CF=Cognitive functioning, SF= Social functioning *p<0.05

In terms of functional scales and clinical characteristics of the participants, it was found that there was no significant mean difference across the functional scales and patient status. However, participants with stage I cervical cancer scored a significantly higher mean in GQoL, role and social functioning. Cognitive function of patients with FIGO stage III cervical cancer was found to have significant mean difference with patients who had stage IV cervical cancer. Patients diagnosed 5 years and over exhibited a significantly higher score on all other functional items except emotional and cognitive functioning scales. There was a significant mean difference in the treatments taken and three of the functioning scales. Patients who have taken chemotherapy showed the least mean for GQoL (Mean ±SD=42.70±23.14) and social functioning (Mean ±SD=30.20±23.74) while patients who have taken radiotherapy showed the least mean for cognitive functioning with a Mean ±SD=76.80±28.31 (Table 10).

Table 9: Mean differences of EORTC QLQ-C30 functional scale with clinical characteristics of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	GQOL	PF	RF	EF	CF	SF
Admission status						
New admission	44.88±25.9	53.42±28.1	45.11±34.6	52.22±35.4	79.77±27.0	35.33±30.9
Follow up	49.18±23.2	52.90±26.1	47.61±34.4	58.25±34.3	79.88±259	41.54±30.8
<i>p-value</i>	0.16	0.88	0.57	0.17	0.97	0.12
Patient status						
Inpatient	48.85±23.7	53.38±26.3	47.70±34.4	57.69±34.0	79.85±26.2	40.96±31.0
Outpatient	41.66±24.0	47.46±29.7	37.33±34.1	47±38.1	80±25.4	32±28.4
<i>p-value(t)</i>	0.14	0.28	0.15	0.13	0.98	0.16

Stage						
Unknown	56.81±35.7	59.39±34.9	48.48±43.1	65.15±34.3	86.36±20.8	45.45±42.8
Stage I	65±19.9	67.33±25.0	76.66±27.4	70±28.38	83.33±22.2	75±28.5
Stage II	52.01±24.6	53.48±28.6	49.74±37.8	56.07±35.5	80.74±25.7	44.96±33.9
Stage III	50.46±22.4	56.79±24.4	50.61±32.4	61.88±31.7	84.56±22.0	42.74±29.2
Stage IV	41.60±21.4	48.24±24.9	39.58±30.8	52.77±35.8	75.11±29.1	31.59±25.2
<i>p-value</i>	0.00*	0.03*	0.00*	0.17	0.05*	0.00*
Time since diagnosis						
Less than 12 months	47.54±23.5	54.25±25.4	46.61±34.1	57.18±34.6	80.90±25.6	38.12±30.1
1 to 5 years	47.24±22.4	48.71±27.9	45.76±34.4	55.25±34.2	76.66±27.3	41.79±30.09
5 years and above	77.77±25.2	73.33±22.3	69.44±35.4	74.30±35.07	90.27±20.6	69.44±38.8
<i>p-value</i>	0.00*	0.04*	0.07	0.19	0.12	0.02*
Treatment						
S	59.44±25.5	71.55±24.3	67.77±38.5	60±30.0	90±16.4	60±36.6
Ch	42.70±23.1	47.08±22.3	41.66±31.6	59.89±34.1	84.37±17.7	30.20±23.7
R	48.53±23.0	52.86±25.4	45.61±33.7	57.55±34.8	76.80±28.3	38.49±29.6
S&Ch	64.16±32.2	61.33±34.3	51.66±43.3	64.16±43.0	90±31.62	66.66±40.8
Ch&R	50.87±21.6	51.75±30.5	53.07±37.5	57.45±33.9	80.70±20.6	53.07±32.3
S,Ch&R	58.75±26.8	59.66±22.6	59.16±32.6	75±27.1	95±15.3	48.33±30.0
None	44.17±22.5	50.42±26.6	43.48±33.3	52.81±34.8	78.94±26.3	35.08±29.1
<i>p-value</i>	0.01*	0.07	0.08	0.23	0.04*	0.00*
Comorbid conditions						
Yes	44.91±23.6	50.28 ±26.9	39.26± 33.1	51.27± 35.7	77.40±26.2	40.67±29.0
No	48.98±23.7	53.46 ±26.4	48.50 ±34.5	58.14±34.3	80.28±26.1	40.3± 31.28
<i>p-value</i>	0.22	0.39	0.06	0.16	0.43	0.94

*P value <0.05 is significant S=Surgery, Ch=Chemotherapy, S&Ch=Surgery and chemotherapy, Ch&R=Chemotherapy and surgery, S, CH&R=Surgery, Chemo and Radiation therapy

Mean differences in EORTCQLQ-C30 symptom scale with socio-demographic and clinical characteristics

As shown in Table 11 the mean scale of nausea and vomiting among patients in age category of 25-54 was higher than the mean in the other age categories. These differences were statistically significant. The mean symptom scales of the EORTC QLQ-C30 showed significant differences with marital status. In this regard mean of the fatigue scale showed a higher result among the single than the other categories. Similarly, the mean scales of insomnia and loss of appetite showed significant differences when we compared married and singles. The education status resulted in a significant mean difference on fatigue, pain and loss of appetite scales in patients with cervical cancer at TASH. In connection with this, those who could not read and write had higher mean scores with respect to fatigue, pain and loss of appetite as compared to other educational status categories.

Table 10: Mean EORTC QLQ-C30 Symptom scales with sociodemographic characteristics and households' income level of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	Fatigue	Nausea and Vomiting	Pain	Dyspnea	Insomnia	Appetite loss	Constipation	Diarrhea	Financial difficulty
Age Category									
25-54	57.29±28.4	25.36±32.09	61.44±31.2	32.31±32.1	47.39±38.9	55.94±39.1	54.78±40.7	8.26±22.3	72.02±35.0
55-64	58.33±27.4	18.47±30.3	59.02±29.3	31.38±32.1	46.94±39.7	51.66±38.8	52.22±42.2	5.27±19.3	65±35.8
>65	54.73±28.7	13.58±26.3	53.70±30.4	23.45±31.4	43.20±40.2	54.32±41.1	54.32±37.9	8.02±24.1	64.19±35.3
<i>p-value</i>	0.74	0.02*	0.24	0.18	0.78	0.63	0.86	0.46	0.12
Marital status									
Single	72±35.03	6.66±14.90	46.66±18.25	6.66±14.9	0.0000	0.0000	26.66±36.51	0.0000	66.66±40.28
Married	65±35.8	20.95±30.6	59.36±30.9	29.52±31.2	49.20±39.4	52.53±39.3	57.61±40.0	8.41±23.2	68.88±35.9
Divorced	64.19±35.3	23.43±30.2	60.62±29.1	34.29±31.8	45.89±38.8	58.45±36.3	49.27±41.4	5.79±20.5	72.94±33.9
Widowed	59.44±30.1	22.64±33.0	59.97±31.7	31.33±33.9	45.01±39.2	57.26±40.0	51.28±41.4	6.83±20.3	66.66±35.5
<i>p-value</i>	0.04*	0.66	0.80	0.26	0.04*	0.09	0.15	0.69	0.71
Educational status									
Unable to read and write	60.06±26.7	23.54±32.0	62.51±29.1	34.40±33.4	48.75±39.2	59.78±38.4	55.51±40.9	6.88±21.4	71.17±34.5

Variables	Fatigue	Nausea and Vomiting	Pain	Dyspnea	Insomnia	Appetite loss	Constipation	Diarrhea	Financial difficulty
Can read and write	47.61±27.8	17.85±27.5	56.54±31.8	26.19±30.5	41.66±36.9	51.19±35.6	64.28±37.3	8.33±23.3	70.23±39.8
Primary	56.61±30.8	21.82±33.2	59.12±30.8	20.63±26.4	52.38±42.3	39.68±39.1	46.03±42.2	11.90±26.3	67.46±34.9
Secondary	50.45±33.9	14.86±25.6	50.0±36.8	25.22±26.5	33.33±36	41.44±39.60	50.4±40.5	2.7±12.1	57.6±34.8
Higher	42.36±24.7	12.5±23.17	39.58±28.4	16.66±24.3	35.4±37.45	35.4±41.2	37.5±36.2	12.5±26.8	56.2±41.7
<i>p-value</i>	0.01*	0.33	0.01*	0.13	0.10	0.00*	0.15	0.33	0.13
Occupation									
Government employee	38.16±28.3	7.24±13.1	42.02±31.7	23.18±29.1	31.88±38.2	36.23±38.8	34.78±35.5	10.14±23.4	49.27±41.2
Private	55.55±27.7	18.33±31.8	51.66±38.0	13.33±23.3	23.33±35.3	36.66±39.90	36.66±39.9	10±22.4	73.33±36.3
Merchant	50.67±30.7	18.69±29.8	54.47±32.2	26.82±31.8	40.65±39.7	46.34±40.7	53.65±40.7	10.56±28.3	58.53±41.2
Retired	51.85±27.7	5.55±11.7	42.59±22.2	11.11±16.6	51.85±44.4	22.22±28.8	25.92±43.3	7.40±22.2	51.85±32.6
Farmer	60.33±24.6	22.68±32.8	62.61±28.4	31.71±31.6	46.75±39.8	59.25±38.7	60.18±39.8	7.87±22.9	73.37±32.6
Housewife	59.62±29.7	25.30±32.1	62.29±31.3	32.92±32.8	51.21±38.0	57.92±37.8	53.45±41.5	6.09±19.2	70.12±36.2
Other	52.99±24.0	15.38±25.8	60.25±25.0	48.71±37.5	48.71±39.9	51.28±46.3	58.97±33.7	0.00	79.48±28.9
<i>p-value</i>	0.01*	0.09	0.02*	0.04*	0.12	0.01*	0.02*	0.74	0.01*

Average Household income (ETB)

Variables	Fatigue	Nausea and Vomiting	Pain	Dyspnea	Insomnia	Appetite loss	Constipation	Diarrhea	Financial difficulty
<600	59.38±28.4	22.78±31.7	62.42±30.7	33.89±31.6	49.71±39.2	58.00±38.4	54.99±41.1	7.53±22.0	69.30±35.2
>600	55.19±27.7	21.04±30.8	57.14±30.5	28.11±31.8	44.39±39.2	50.99±39.6	52.22±40.7	7.52±21.9	68.35±35.7
<i>p-value</i>	0.14	0.58	0.09	0.73	0.18	0.78	0.50	0.99	0.79

On the clinical characteristics of patients; Fatigue, Pain and loss of appetite showed significant mean differences across FIGO stages. Stage IV showing the highest symptoms while stage I had the least. Patients whose diagnosis was longer than 5 years showed a significantly low mean on the scales of fatigue, pain, loss of appetite and financial difficulty scales. On the treatment options all of the symptom scales with the exception of loss of appetite and nausea and vomiting exhibited a significant mean difference among groups. Least symptom score was reported with patients who underwent surgery. The least diarrhea scale was observed by patients who have not yet taken any treatment while the patients who have taken concurrent chemo-radiation scored the highest scale for diarrhea. (Table 12)

Table 11: Mean differences in EORTC QLQ-C30 symptom scale with clinical characteristics of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	Fatigue	Nausea and Vomiting	Pain	Dyspnea	Insomnia	Appetite loss	Constipation	Diarrhea	Financial difficulty
Admission Status									
New Admission	61.92±24.7	17.55±28.19	60.00±29.38	33.77±33.9	51.11± 42.2	57.33± 39.3	66.22± 36.9	5.33± 19.7	72.88±33.1
Follow up	56.19±28.8	22.69± 31.7	59.62±30.96	30.19 ±31.6	45.69 ±38.5	53.79± 39.3	51.16 ±41.1	7.8± 22.16	67.98±35.9
<i>p-value</i>	0.14	0.19	0.71	0.30	0.05	0.60	0.00	0.94	0.67
Patient status									
Inpatient	57.02±28.1	21.20±30.4	59.39±30.5	30.51±31.9	46.38±39.2	53.88±39.3	53.17±41.0	7.67±22.3	69.48±35.6
Outpatient	61.33±28.34	28±39.29	66.66±30.42	36±35.90	53.33±39.67	62.66±38.87	65.33±36.61	2.66±9.22	60.00±31.91

Variables	Fatigue	Nausea and Vomiting	Pain	Dyspnea	Insomnia	Appetite loss	Constipation	Diarrhea	Financial difficulty
<i>p-value</i>	<i>0.46</i>	<i>0.29</i>	<i>0.25</i>	<i>0.41</i>	<i>0.39</i>	<i>0.28</i>	<i>0.15</i>	<i>0.27</i>	<i>0.19</i>
Stage									
Unknown	45.45±35.9	10.60±17.1	43.93±37.4	24.24±33.6	54.54±47.7	42.42±44.9	42.42±49.6	15.15±34.5	51.51±47.9
Stage I	44.44±25.6	5±15.8	35±24.1	13.33±17.2	43.33±41.7	33.33±41.5	30±42.8	16.66±36.	50±42.3
Stage II	54.52±31.3	20.54±31.0	57.49±32.4	28.68±32.7	44.96±39.0	46.51±40.9	52.71±41.3	5.94±17.4	64.08±37.4
Stage III	56.27±27.3	21.14±30.5	55.24±30.0	28.70±30.3	43.82±36.6	54.93±37.3	51.54±40.6	7.40±23.3	70.67±35.2
Stage IV	62.5±24.4	25.11±32.8	68.63±26.3	36.34±32.9	50.69±40.5	63.88±36.6	59.72±38.9	7.40±21.7	74.53±31.2
<i>p-value</i>	<i>0.04*</i>	<i>0.18</i>	<i>0.00*</i>	<i>0.07</i>	<i>0.59</i>	<i>0.01*</i>	<i>0.10</i>	<i>0.44</i>	<i>0.02*</i>
Time since diagnosis									
Less than 12 months	56.87±27.2	22.22±31.5	60.08±30.1	30.14±32.0	47.89±39.3	55.68±39.7	56.44±39.7	6.64±20.8	71.00±33.8
1- 5 years	61.19±27.9	21.92±30.9	62.56±29.7	33.84±32.6	45.89±38.9	55.38±37.9	52.05±42.3	9.48±24.2	68.20±36.3
5 years and above	25±31.1	11.11±22.8	20.83±27.6	13.88±22.2	25±35.1	19.44±30.0	22.22±35.7	0.00	36.11±41.1
<i>p-value</i>	<i>0.00*</i>	<i>0.48</i>	<i>0.00*</i>	<i>0.10</i>	<i>0.14</i>	<i>0.01*</i>	<i>0.14</i>	<i>0.24</i>	<i>0.03*</i>
Treatment									

Variables	Fatigue	Nausea and Vomiting	Pain	Dyspnea	Insomnia	Appetite loss	Constipation	Diarrhea	Financial difficulty
Surgery	40±29.9	6.66±18.6	36.66±32.8	26.66±38.2	17.77±27.7	37.77±45.1	31.11±36.6	0.0000	60±38.21
Chemotherapy	63.19±25.2	32.29±39.1	70.83±22.3	41.66±31.0	43.75±37.9	62.5±38.2	66.66±29.8	2.08±8.3	85.41±17.0
Radiotherapy	57.11±28.45	23.09±31.9	59.25±31.5	31.57±32.3	46.39±39.9	54.58±39.5	55.36±39.9	8.18±21.6	69.98±35.1
Surgery and Chemotherapy	41.11±35.5	6.66±16.1	40±39.4	16.66±32.3	26.66±40.9	33.33±35.1	26.66±37.8	0.0000	46.66±47.6
Chemo-radiation	58.18±31.2	21.49±32.8	64.91±27.0	24.56±30.6	53.50±38.3	61.40±35.9	44.73±43.3	17.54±33.5	57.01±39.4
Surgery, Chemo-radiotherapy	41.11±29.30	25±27.30	40±32.62	21.66±27.09	31.66±38.19	43.33±42.02	36.66±43.12	8.33±26.21	55.±43.62
None	62.23±24.5	21.30±30.6	64.41±27.4	33.58±31.9	52.88±37.8	56.89±38.4	60.90±40.0	5.26±19.1	73.43±31.7
<i>p-value</i>	<i>0.02*</i>	<i>0.22</i>	<i>0.00*</i>	<i>0.23</i>	<i>0.01*</i>	<i>0.14</i>	<i>0.00*</i>	<i>0.03*</i>	<i>0.01*</i>
Comorbid conditions									
<i>Yes</i>	<i>60.45±24.17</i>	<i>20.90± 30.1</i>	<i>62.71 ±29.2</i>	<i>27.68± 29.7</i>	<i>49.15± 37.3</i>	<i>60.45 ±39.8</i>	<i>55.36 ±40.4</i>	<i>9.60 ±25.5</i>	<i>77.96±28.7</i>
<i>No</i>	<i>56.71±28.78</i>	<i>21.88± 31.1</i>	<i>59.17± 30.8</i>	<i>31.40±32.4</i>	<i>46.28 ±39.6</i>	<i>53.43± 39.1</i>	<i>53.71 40.90</i>	<i>6.95±21.03</i>	<i>67.34±36.2</i>
<i>p-value</i>	<i>0.35</i>	<i>0.82</i>	<i>0.41</i>	<i>0.41</i>	<i>0.60</i>	<i>0.20</i>	<i>0.77</i>	<i>0.38</i>	<i>0.33</i>

Mean differences in EORTCQLQ-CX24 functional scale with Sociodemographic and Socio-economic characteristics of patients

The results in Table 13 showed from the functioning scales a significant mean difference was found in the body image of those falling under the age category of 65 years old, marital status with married reporting the least mean (46.98±39.2) and occupation of the participants. A minimum and significant sexual activity score was found and participants falling under the age category of 65 and above, divorced and those with no education had the highest difference in the sexual activity scale. Average monthly household income did not exhibit a significant difference in the scales. Even though sexual enjoyment and vaginal function fall under this category, there was no significant mean difference observed among those who were able to respond to the questions.

Table 12: Mean differences in EORTC QLQ-CX24 functional scale with sociodemographic characteristics of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

	Body Image	Sexual activity	Sexual enjoyment	Sexual/vaginal function
Age Category				
25-54	46.03±39.7	8.15±21.8	41.66±29.3	58.59±30.1
55-64	56.48±37.5	5±19.15	55.55±33.3	85.18±17.0
>65	54.52±35.2	0.00	0.00	0.00
<i>p-value</i>	0.04*	0.02*	0.16	0.23
Marital status				
Single	53.33±50.5	41.66±5	66.6±47.1	25±11.0
Married	46.98±39.2	10.15±24.4	43.8±30.1	66.66±29.3
Divorced	52.49±37.4	0.4831±4.0	33.3±0	58.3±0.0
Widowed	54.22±38.32	1.13±8.6	0.00	0.00
<i>p-value</i>	0.04*	0.00*	0.56	0.15
Educational status				
Unable to read and write	48.12±38.3	4.16±16.0	43.93±29.7	57.19±29.1
Can read and write	52.77±43.25	2.38±12.59	0.00	0.00

	Body Image	Sexual activity	Sexual enjoyment	Sexual/vaginal function
Primary education	52.38±36.9	7.93±24.2	26.66±27.8	71.66±19.1
Secondary	60.36±38.4	11.71±27.4	61.90±29.9	86.90±17.2
Higher education	54.86±43.7	29.16±34.15	42.85±31.7	59.52±39.2
<i>p-value</i>	0.43	0.00*	0.26	0.12
Occupation				
Government employee	68.59±38.7	13.04±26.0	33.33±29.8	51.38±39.2
Private	67.77±33.3	23.33±38.6	44.44±38.4	72.22±19.2
Merchant	39.83±38.4	7.31±20.4	41.66±31.91	75±13.6
Retired	79.01±25.1	0.00	0.00	0.00
Farmer	43.04±35.6	4.42±15.4	45.23±28.0	64.88±32.8
Housewife	56.57±39.4	6.09±20.9	50±33.9	64.88±28.7
Other	21.36±33.47	0.0000	0.00	0.00
<i>p-value</i>	0.00*	0.31	0.78	0.87
Average monthly household income(ETB)				
<600	50.84±39.5	4.14±16.9	46.15±37.3	64.10±30.1
>600	49.53±38.0	8.02±21.9	44.04±27.2	64.58±30.1
<i>p-value</i>	0.74	0.55	0.84	0.96

*Other = Beggars, house maids, commercial sex workers P<0.05 considered significant

Mean differences in EORTC QLQ-CX24 functional scales with clinical characteristics.

It can be observed on table 14 that the clinical characteristics of the patients exhibited a significant mean difference in the body image scale and patients whose time of diagnosis was 5 years and above. Patients whose time of diagnosis was 5 years and above scored a good body image (Meaning SD =91.66±11.78). Even though its very low, sexual activity had a significant mean difference on the stage category and treatments taken. Stage II patients had the highest mean value and those patients who took surgery and chemo-radiation had the highest sexual activity. Patients who took chemo therapy had the highest sexual enjoyment compared to the rest.

Table 13: Clinical characteristics with EORTC QLQ-CX24 functional scale of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	Body Image	Sexual activity	Sexual enjoyment	Sexual/vaginal function
Admission type				
New admission	37.18±36.0	3.11±13.6	22.22 ± 19.2	69.44 ±19.2
Follow up	53.42±38.7	6.80±20.7	46.49 ± 30.5	64.03 ±30.5
<i>p-value</i>	0.01*	0.14	0.18	0.76
Patient status				
Inpatient	50.38±38.51	6.36±20.06	44.71±30.37	64.43±29.75
Outpatient	48.00±43.71	2.66±13.33	0.00	0.00
<i>p-value</i>	0.77	0.36		
Stage				
Unknown	47.47±40.08	0.00	0.00	0.00
Stage I	70±36.6	6.66±14.05	83.33±11.7	33.33±0.00
Stage II	46.25±39.2	10.59±24.9	65.15±32.0	36.36±25.00
Stage III	54.01±36.2	3.39±15.0	45.83±25.6	72.22±32.7
Stage IV	49.80±39.7	4.19±17.1	68.33±27.9	46.66±35.8
<i>p-value</i>	0.10	0.04*	0.07	0.36
Time since diagnosis				
Less than 12 months	63.76±24.4	5.61±19.01	50.72±33.1	63.76±24.4
1 to 5 years	66.11±34.2	6.20±19.4	35.55±23.4	66.11±34.2
5 years and above	91.66±11.78	13.88±33.2	66.66	91.66±11.7
<i>p-value</i>	0.06	0.36	0.19	0.42
Treatment				
Surgery	60.74±38.4	4.44±17.2	66.66	75±29.4
Chemotherapy	52.77±40.0	0.00	35.18±24.1	0.00
Radiotherapy	49.77±38.5	5.45±17.6	66.66	50.92±29.4

Surgery/Chemo	61.11±46.9	16.66±36.0	77.77±34.42	100±2
Chemo-radiation	56.72±37.7	11.40±28.2	55.55±27.2	77.77±23.3
Surgery/Chemo/radio	47.22±39.7	20.00	29.62	73.61±38.1
None	47.61±38.6	3.50±14.36	96±26.0	71.29±22.4
<i>p-value(t)</i>	<i>0.71</i>	<i>0.00</i>	<i>0.01</i>	<i>0.18</i>
Comorbid conditions				
Yes	42.74 ±39.3	5.08±17.30	33.33 ± 33.33	69.44± 9.62
No	51.71 ±38.5	6.29 ±20.10	45.61 ± 30.43	64.03 ±30.82
<i>p-value</i>	<i>0.10</i>	<i>0.39</i>	<i>0.50</i>	<i>0.76</i>

Mean differences in EORTCQLQ-CX24 symptom scale with socio-demographic and clinical characteristics

On the analysis of the score of symptom scales of the EORTC QLQ-CX24 with the age category and marital status, only the sexual worry scale showed a significant mean difference. Participants falling in the age group of 25 to 54 years old showed a mean difference from the rest of the age category. Married, widowed and single patients had a significant mean difference from the marital status category. Income category of patients did not indicate a significant mean different among the scales (Table 15).

Table 14: Sociodemographic and Clinical characteristics with EORTC QLQ-CX24 symptom scale of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	Symptom experience	Lymphadenoma	Peripheral neuropathy	Menopausal symptoms	Sexual worry
Age Category					
25-54	43.57±22.0	13.04±27.4	44.92±38.0	57.68±34.9	40.72±46.9
55-64	42.32±24.2	13.05±29.7	40±40.90	56.38±35.5	25.27±40.7
>65	39.05±20.2	10.49±24.9	36.41±40.5	46.29±37.9	20.98±40.0
<i>p-value</i>	<i>0.41</i>	<i>0.82</i>	<i>0.27</i>	<i>0.11</i>	<i>0.01</i>
Marital status					
Single	23.03±18.8	13.33±18.2	73.33±27.8	33.33±47.1	80±44.7

Married	44.34±23.5	10.31±25.9	43.96±39.5	57.46±34.5	41.74±46.3
Divorced	42.51±20.2	17.39±30.0	44.44±36.9	60.38±32.9	27.53±43.8
Widowed	39.80±21.4	13.96±29.4	36.18±40.2	50.14±38.0	20.51±39.1
<i>p-value</i>	0.77	0.29	0.89	0.89	0.00*
Educational status					
Unable to read and write	44.47±23.0	12.45±27.1	43.53±39.5	58.00±35.5	31.07±44.5
Can read and write	41.66±20.9	3.57±13.8	41.66±36.9	53.57±37.7	32.14±47.5
Primary	38.16±20.8	16.66±33.9	44.44±41.4	54.76±36.6	38.09±47.4
Secondary	40.37±20.4	17.11±33.9	32.43±35.5	45.04±34.4	35.13±41.5
Higher education	28.03±19.87	12.5±20.63	39.58±42.54	47.91±32.13	62.5±43.67
<i>p-value</i>	0.03*	0.30	0.59	0.25	0.92
Occupation					
Government	31.35±20.5	15.94±28.1	37.68±38.0	44.92±35.6	34.78±46.5
Private	25.15±13.1	10±22.4	36.66±33.1	33.33±35.1	50±47.7
Merchant	43.45±19.2	11.38±24.2	38.21±36.9	52.03±36.5	36.58±47.0
Retired	27.94±17.7	11.11±33.3	22.22±44.0	22.22±37.2	18.51±37.6
Farmer	44.59±19.5	9.95±23.3	44.67±39.0	59.49±32.3	30.06±43.3
Housewife	43.69±25.3	15.04±32.0	41.66±40.6	57.92±37.0	33.33±45.0
Other	47.31±25.4	15.38±25.8	64.10±28.7	58.97±33.7	53.84±51.8
<i>p-value</i>	0.01	0.78	0.25	0.01*	0.42
Average household income (ETB)					
<600	43.29±23.95	12.80±28.18	43.87±40.38	53.67±36.24	32.76±45.84
>600	41.79±21.4	12.13±27.0	41.78±38.6	57.14±35.1	34.71±44.4
<i>p-value</i>	0.51	0.81	0.60	0.34	0.67

Mean differences in EORTCQLQ-CX24 Symptom scale with clinical characteristics

Symptom experience and peripheral neuropathy resulted in a significant mean difference of the participants on different stages of cervical cancer. There is significant mean difference in treatment and lymph adenoma, and sexual worry. Patients who have had surgery had the lowest lymph adenoma symptom (Mean and SD= 6.66±18.68), while patients who took chemotherapy had the least sexual worry (Mean and SD=17.54±33.54). However, participants diagnosed 5 years and above had a significant difference in symptom experience. (Table 16)

Table 15: Mean difference in EORTCQLQ-CX24 Symptom scale with clinical characteristics of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	Symptom experience	Lymphadenoma	Peripheral neuropathy	Menopausal Symptom	Sexual worry
Admission type					
New Admission	45.97 ±20.1	9.33 ±24.2	41.77± 40.6	60.44± 37.8	39.55± 47.3
Follow up	41.84± 23.0	13.51 ±28.5	42.37 ±39.0	54.57± 35.0	31.91 ±44.2
<i>p-value</i>	0.15	0.24	0.95	0.19	0.18
Patient status					
Inpatient	42.51±22.54	12.08±26.78	43.29±39.26	55.46±35.69	33.77±45.06
Outpatient	45.21±21.67	22.66±39.34	28±38.10	61.33±35.59	30.66±45.05
<i>p-value(t)</i>	0.56	0.07	0.60	0.42	0.39
Stage					
Unknown	29.09±40.5	13.33±29.8	13.33±29.8	13.33±29.8	40±54.7
Stage I	22.72±14.30	13.33±32.20	60±34.42	53.33±42.16	40±46.61
Stage II	39.22±22.2	13.43±28.4	42.63±40.1	55.29±35.4	37.46±45.4
Stage III	44.89±22.6	12.34±26.0	36.11±37.8	55.24±35.6	29.01±43.9
Stage IV	46.21±21.1	12.96±28.9	47.68±39.5	58.33±35.1	31.48±44.7
Recurrent	43.43±18.9	0.00	22.22±27.2	61.11±38.9	66.66±51.6
<i>p-value</i>	0.03*	0.93	0.04	0.15	0.32
Treatment					
S	25.05±23.3	6.66±18.6	33.33±33.3	33.33±41.7	28.88±43.4

Variables	Symptom experience	Lymphadenoma	Peripheral neuropathy	Menopausal Symptom	Sexual worry
CT	50.37±20.0	14.58±29.7	29.16±36.2	56.25±33.8	31.25±42.9
RT	41.02±22.1	14.61±31.1	43.85±40.3	53.80±34.5	34.11±45.0
S&RT	25.45±25.1	10±22.4	36.66±36.6	36.66±42.8	30±48.3
C&RT	41.14±24.8	14.91±30.7	39.47±39.4	63.15±34.4	17.54±33.5
S,CT&RT	27.42±18.3	10±24.4	56.66±34.3	50±38.2	58.73±49.3
None	49.69±19.8	10.77±23.7	41.85±39.7	60.65±34.7	34.33±46.2
<i>p-value</i>	0.37	0.05*	0.05*	0.45*	0.06
Time since diagnosis					
Less than 12 months	44.35±22.2	11.36±25.3	42.01±38.8	57.98±35.3	35.88±45.59
1 to 5 years	41.58±21.9	15.64±31.9	44.61±40.3	53.33±35.1	28.46±43.5
5 years and above	15.90±19.7	11.11±29.5	19.44±30.0	30.55±38.8	30.55±43.7
<i>p-value</i>	0.00*	0.35	0.10	0.22	0.29
Co morbid condition					
Yes	40.31 ±20.5	18.64± 31.1	46.32± 39.5	55.36±36.9	33.89±44.8
No	43.00± 22.8	11.72± 27.0	41.56±39.5	55.71±35.4	33.23±44.9
<i>p-value</i>	0.39	0.77	0.39	0.94	0.91

6.2.4. Predictive factors of Global Quality of life

During the bivariate analysis, all variables with p -value < 0.25 were included for the multivariable logistic regression. On the multi-variable analysis, only four of the variables showed association with the GQoL. Accordingly, Physical functioning (AOR=4.98, 95%CI=2.16-11.49), emotional functioning (AOR=5.25, 95%CI=2.26-12.17), pain (AOR=5.79, 95%CI=2.30-14.57) and symptom experience (AOR=4.58, 95%CI=1.95-10.79) had shown a significant association with GQoL. In other words, patients who had an affected physical functioning are 2.1 times more likely to affect the GQoL, such as the difficulty to walk is likely result in an affected GQoL. A persons emotional wellbeing is also a predictive factor that will impact the GQoL, an emotionally affected person is

5.2 times more likely to have their GQOL affected. The feeling of pain has 5.7 times likely chance of affecting the GQoL as well as symptom experience which has a 4.58 times risk of affecting the GQoL (Table 17).

Table 16: Binary and multivariable logistic regression analysis to observe association between (socio-demographic, medical characteristics) variables and global QoL of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	GQOL		Odds Ratio (95%CI)	
	Affected	Unaffected	COR	AOR
Marital status				
Single	2(0.6%)	3(4.7%)	0.15(0.24-0.98)	
Married	181(53.7%)	29(45.3%)	1.44(0.78-2.65)	
Divorced	59(17.5%)	10(15.6%)	1.36(0.60-3.0)	
Widowed	59(17.5%)	10(15.6%)	1	
Educational status				
Unable to read and write	246(72.4%)	35(54.7%)	9.03(3.16-25.80)	
Informal education	23(6.8%)	5(7.8%)	5.91(1.48-23.56)	
Primary education	35(10.3%)	7(10.9%)	6.42(1.79-23.08)	
Secondary	29(8.5%)	8(12.5%)	4.66(1.32-16.43)	
Higher education	7(2.1%)	9(14.1%)	1	
Occupation				
Government	14(4.1%)	9(14.1%)	0.28(0.50-1.58)	
Private	7(2.1%)	3(4.7%)	0.42(0.56-3.21)	
Merchant	34(10.0%)	7(10.9%)	0.88(0.15-4.89)	
Retired	6(1.8%)	3(4.7%)	0.364(0.04-2.81)	
Farmer	134(39.4%)	10(15.6%)	2.43(0.47-12.53)	
Housewife	134(39.4%)	30(46.9%)	0.812(0.171-3.85)	
Other	11(3.2%)	2(3.1%)	1	

The association between the GQOL and medial characteristics resulted in a significant association in the FIGO stage of patients and treatments taken. However, in the multi-variable associations there was no significant association between Medical characteristics of patient and GQOL.

Table 17: Binary and multivariate logistic regression analysis between clinical variables and GQOL of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables	GQOL		Odds Ratio (95%CI)	
	Affected	Unaffected	COR	AOR
Stage				
Stage I	7(2.1%)	3(4.8%)	1.33(0.21-8.28)	
Stage II	100(29.5%)	29(46.0%)	1.97(0.53-7.20)	
Stage III	91(26.8%)	17(27.0%)	3.05(0.80-11.60)	
Stage IV	134(39.5%)	10(15.9%)	7.65(1.91-30.63)	
Unknown	7(2.1%)	4(6.3%)	1	
Treatment				
None	119(35%)	14(21.9%)	3.09(0.867-11.02)	
CT	15(4.4%)	1(1.6%)	5.45(0.53-55.80)	
RT	143(42.1%)	28(43.8%)	1.85(0.55-6.25)	
S&CT	5(1.5%)	5(7.8%)	0.36(0.67-1.19)	
C&RT	31(9.1%)	7(10.9%)	1.61(3.94-6.58)	
S,CT&RT	16(4.7%)	5(7.8%)	1.16(0.25-5.33)	
Surgery	11(3.2%)	4(6.3%)	1	
Time since diagnosis (t)				
Less than 12 months	227(67%)	34(53.1%)	13.3(3.84-46.75)	
1 to 5 years	108(31.9%)	22(34.4%)	9.81(2.71-35.48)	

Above 5 years 4(1.2%) 8(12.5%) 1

Table 18: Binary and multivariate logistic regression analysis between EORTC QLQ-C30 scales of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables		GQOL		COR (95%CI)	AOR (95% CI)
Functioning scales		Affected	Unaffected		
Physical	Affected	297(87.4%)	25(39.1%)	10.77(5.94- 19.54)	4.98(2.16-11.49)
	Unaffected	43(12.6%)	39(60.9%)	1	1
Role	Affected	290(85.3%)	21(32.8%)	11.8(6.50- 21.68)	
	Unaffected	50(14.7%)	43(67.2%)	1	
Emotional	Affected	227(66.8%)	15(23.4%)	6.52(3.52-12.20)	5.25(2.26-12.17)
	Unaffected	113(33.2%)	49(76.6%)	1	1
Cognitive	Affected	134(39.4%)	10(15.6%)	3.51(1.72-7.13)	
	Unaffected	206(60.6%)	54(84.4%)	1	
Social	Affected	316(92.9%)	30(46.9%)	14.92(7.84-28.38)	
	Unaffected	24(7.1%)	34(53.1%)	1	
Farigue	Affected	313(92.1%)	27(42.2%)	15.88 (8.43- 29.91)	
	Unaffected	27(7.9%)	37(57.8%)	1	
Nausea and vomiting	Affected	132(38.8%)	6(9.4%)	6.13(2.57-14.61)	
	Unaffected	208(61.2%)	58(90.6%)	1	
Pain	Affected	318(93.5%)	25(39.1%)	22.54(11.62-43.73)	5.79(2.30-14.57)
	Unaffected	22(6.5%)	39(60.9%)	1	1
Dyspnea	Affected	212(62.4%)	14(21.9%)	5.91(3.14-11.12)	
	Unaffected	128(37.6%)	50(78.1%)	1	
Insomnia	Affected	250(73.5%)	25(39.1%)	4.33(2.48-7.5)	
	Unaffected	90(26.5%)	39(60.9%)	1	
	Affected	273(80.3%)	26(40.6%)	5.95(3.38-10.48)	

Loss of appetite	Unaffected	67(19.7%)	38(59.4%)	1
Constipation	Affected	256(75.3%)	25(39.1%)	4.75(2.71-8.31)
	Unaffected	84(24.7%)	39(60.9%)	1
Diarrhea	Affected	47(13.8%)	2(3.1%)	4.97(1.17-21.01)
	Unaffected	293(86.2%)	62(96.9%)	1
Financial Difficulty	Affected	306(90.0%)	41(64.1%)	5.04(2.71-9.39)
	Unaffected	34(10.0%)	23(35.9%)	1

Table 19: Binary and multivariate logistic regression analysis to association of GQOL and EORTC QLQ CX 24 scales of patients with cervical cancer at TASH, Addis Ababa, Ethiopia, 2018.

Variables		GQOL			AOR
		Affected	Unaffected	OR	
Body Image	Affected	242(71.2%)	22(34.4%)	4.71(2.67-8.30)	
	Unaffected	98(28.8%)		1	
Sexual Activity	Affected	334(98.5%)	61(95.3%)	3.28(0.76-14.10)	
	Unaffected	5(1.5%)	3(4.7%)	1	
Sexual/vaginal	Affected	16(57.1%)	4(30.8%)	3.00(0.74-12.11)	
	Unaffected	12(42.9%)	9(69.2%)	1	
Symptom function					
Symptom experience	Affected	279(85.8%)	16(27.6%)	15.92(8.27-30.64)	4.58(1.95-10.79)
	Unaffected	46(14.2%)	42(72.4%)	1	1
Peripheral neuropathy	Affected	222(65.3%)	25(39.1%)	2.93(1.69-5.08)	
	Unaffected	118(34.7%)	39(60.9%)	1	
Menopausal Symptoms	Affected	285(83.8%)	34(53.1%)	4.57(2.58-8.08)	
	Unaffected	55(16.2%)	30(46.9%)	1	

7. Discussion

The main purpose of this study was to assess the HRQOL, associated factors, and utility of cervical cancer patients in Ethiopia. As a precondition to the assessment of the HRQOL of patients, validation of EORTC QLQ-CX24 disease-specific module was performed to establish the psychometric properties of the tool in the Ethiopian patients. This validation study indicated that the EORTC QLQ-CX24 has the acceptability and is a psychometrically robust tool to measure HRQOL specifically in cervical patients.

The results of the validation showed that the EORTC QLQ-CX24 tool was easily understood with 100% compliance. None of the patients refused to fill the questionnaire with no missing responses. Therefore, this can be seen an indicator of the acceptability of the tool for Ethiopian cervical cancer patients. All scales of the questionnaires indicated a strong internal consistency with Cronbach ($\alpha \geq 0.7$) similar to previous studies (Kuljanic *et al.*, 2006; Hua, 2013). Pearson correlation analyses confirmed the satisfactory convergent and discriminant validity of the EORTC QLQ-CX24. The results exhibited a good item convergent and discriminant validity, as the Pearson correlation ($r > 0.40$). Similar to results of study by Greimel *et al.* (2009), the symptom scale, body image and vaginal functioning have good item convergence; this translates as the ability of items to represent or correlate more to their own scales in comparison to other scales.

While all the items including single item, measures have good discriminant validity except for item 53 of the vaginal functioning scale which inquired in regards to pain during sexual intercourse, this item exhibited a higher positive correlation with sexual worry. Sexual/vaginal functioning and sexual enjoyment were optional, that are to be skipped if the woman has not been sexually active during the past 4 weeks prior to interview. Almost 152 (88.8%) of the participants skipped the sexual/vaginal functioning. The non-optional sexuality items were completed by all patients. Similar missing values were found in studies in South Korea and Poland, which might be due to the privacy of the sexuality (Shin *et al.* 2009; Hua, 2013; Paradowska *et al.*, 2014) This indicates that the status of the patients highly influences their sexual activity and functioning. Studies also indicated that cultural boundaries and privacy of the sexuality could have an influence in the determination of sexual functioning and the (Beaton *et al.*, 1976; Conill *et al.*, 1990).

The Pearson correlations between the EORTC QLQ-C30 and the EORTC QLQ-CX24 were strong in majority of the scales and none or weak correlations in other scales. As seen in the Chinese and Polish validation studies the EORTC QLQ-CX24 scores correlated well with another established measure of HRQOL, the EORTC QLQ-C30 core questionnaires, indicating that those scales assessing similar aspects were correlated strongly. While none and weak correlations indicate that the EORTC QLQ-CX24 has unique domains of HRQOL, which are not addressed by the EORTC QLQ-C30. This results are another proof for the development of questionnaires by the EORTC that have to be used together in order to have a complete understanding of the patients quality of life (Hua, 2013; Ayasekara and Rajapaksa, 2008). The result of known group comparison showed that the EORTC QLQ-CX24 disease specific module was able to discriminate between patients with different FIGO disease stages and ECOG-PS as well as patients being on treatment or not.

As the major finding of the study the mean score for GQoL of cervical cancer patients was low which is similar to studies done in Iran and China (Torkzahrani *et al.*, 2013; Huang, 2017) but lower than Indian and Brazilian cervical cancer patients (Dallabri *et al.* 2013). The differences could be due to patients' cultural influence, perception of their illness and diagnosis at late stage. These factors were found to affect in patient outcome (Khalil *et al.*, 2015). It could also be that patients assumption of an exaggerated symptom report will entail more attention from the health care professional.

The functioning domain of EORTCQLQ 30 and EORTCQLQ CX 24 resulted in a score lower than the reference value and the symptom scales besides diarrhea are all higher than the reference values placed by the EORTC group (Scott *et al.*, 2008). Social and sexual functioning was found to have a minimum result among the scales which mirrors to previous findings where patients with cervical cancer found it difficult to interact with their community and engage in sexual activity due to the illness and treatment. This study found only 10.1% of the participants was sexually active which is similar to a study done in Poland where the majority participants were not sexually active (Paradowska *et al.*, 2014). This is not unexpected as sexual activity is among the least reported functioning item in this group of patients.

The result of symptom scales of the EORTC QLQ-C30 and EORTC QLQ-CX24 have found that all of the symptom scales, except for diarrhea and lymph adenoma, were above the reference value

(Scott *et al.*, 2008). This is not unexpected outcome for patients being treated for cervical cancer as a study done in the HRQOL of cervical cancer survivors showed that there were still symptoms of pain in the abdomen, urinary leakage, dyspareunia and menopausal symptoms (Korfage *et al.*, 2009). Similar to the finding in India (Kumar *et al.*, 2007), diarrhea was among the least reported symptoms. However, a study done in UK found diarrhea and fatigue as the most frequently reported symptom (Bjelic-Radisic. *et al*, 2012). The difference between the two group's lies in the fact that majority of the patients in the present study did not receive any treatment. And diarrhea is a symptom associated with the treatment side effect.

Patients who fell under the 25-54 years of age showed a significant mean difference in Body image and sexual activity scales. The mean of these two scales was much lower in comparison to other sub scales in the same age category. This could be interpreted as patients who are younger have a poorer body image and lower sexual/ vaginal functioning in comparison to older groups. This result is supported by Bae and Park (2016) that explained the resulting poorer body image due to the low self-esteem that arises among women who have not yet completed childbearing. Shame and regret were also reported as influencers of the body image of women in the younger age category (Herzog and Wright, 2007).

The present study indicates that GQoL, role functioning, social functioning, sexual activity, fatigue, pain, loss of appetite and symptom experience showed significance differences with the patients educational background. This is similar to the finding of a study done to evaluate the GQoL of cancer patients where educational level was found to be associated with certain domains of GQoL (Pinar, 2003, Quercioli *etal*, 2009 and König *et al.*, 2009). The results can be indicative that patients who are educated hence, with a better understanding of their condition, could have a different perception on their role and emotional functioning which will allow them to be able to interact better in their social life. On the contrary to the finding of the current study, one study done in Ethiopia found no significant relationship between every socio-demographic character including, marital status, income and educational status the patient (Tadele, 2015 and Vrettos *et al.*, 2012). This difference could have been due to the difference of measurement tools, difference of populations.

Patients who were on FIGO stage IV of cervical cancer reported significantly lower mean in role, cognitive and social functioning scales and on the symptom scales and higher report of fatigue, loss of appetite, pain, symptom experience and peripheral neuropathy. Even though some literatures did not show the similar results (Vistad, 2006 and Sowa *et al.*2014), the present study and a study by Xie *et al.*(2013) confirmed higher scores for physical and role functioning with patients that are on earlier stages of cervical cancer. The ability to interact with their community and participate in household tasks declines due to the prevalence of symptoms and lower functionality scores. This can be reflected directly on the role and social functioning of the patients who are on FIGO stage IV.

It was noted in our study that patients who did not receive any treatment reported more symptom experience than those who did. Similarly, a significant mean difference was found among the functional scales of EORTC QLQ-C30 except physical, role, emotional functioning, body image and sexual and vaginal functioning. A study by Bjelic *et al.* (2012) showed different result in that the treatment had affected patients significantly in every scale of EORTC QLQ-C30. On the other hand another study reported that patients did not show significant psychological differences between treatment options (Kobeyashi *et al.*, 2009). Self-esteem was reported to have a significant role in psychological distress and quality of life thus, the researcher's recommended psychological support for this group. Concur to the findings of previous studies (Gotay *et al.*, 2008; Ljuca and Marosevic, 2009), our study indicated that patients had better GQoL, cognitive, social functioning, sexual activity and sexual enjoyment after treatment this is an indicative of an improved HRQoL of patients in comparison to those who are still waiting for treatment.

The results of the study showed that patients reported improved GQoL post treatment of chemotherapy and surgery than radiotherapy and other treatment options. This is also evident in another study that found, compared to surgery only, especially primary radiotherapy was linked with an increased frequency of treatment-related side effects (Korfage *et al.*, 2009). A study done in Japan on psychological distress and HRQOL in cervical cancer survivors after radiotherapy indicated that the trend appeared to be that patients who had radiation therapy had more psychosocial and sexual problems compared with patients undergoing only surgical treatment (Mika *et al.*,2009, Kobayashi, 2009).At a similar range to the finding of the current study the findings of Jensen (2003) indicated that almost 85% patients had lost their sexual interest and half

of the patients were found to have mild to severe painful sexual intercourse (Jensen, 2003). The residual effect of the disease and treatment has a definite effect on the HRQOL of the patients.

In our study, it was shown that the global quality of life was found to have a strong association with physical function. The patients who were able to walk without exhaustion or feeling pain had less chance of reduced GQoL. Similarly, if a patient's emotional function is unaffected, the patients' GQoL will have less chance of being compromised. A study done in Iran found similar predictive factors with the exception of physical functioning (Torkzahrani, 2013). Physical function is an often neglected but integral part of the HRQoL of patients (Kirchheiner, 2013). In Ethiopia, where women play a big role in the household, the physically function ability might have a great impact on the self-satisfaction and HRQoL of patients.

Pain in the EORTC QLQ-C30 scale and Symptom experience from the EORTCQLQ-CX24 were found as predictive factors for GQoL. Studies found a similar result and emphasized that the degree of pain directly affected the GQoL of patients with cervical cancer (Xie *et al.*, 2013; Tadele, 2015). While others indicated that symptom experience had a relevant degree of affecting the GQoL of a patient as well. making pain as significant and other studies concurrent with the relationship of symptom experience and GQoL Satwe *et al.*,2014;Khalil *et al.*,2015). In light of the significance of pain and symptom experience TASH could benefit patient by providing continuous supply of pain and symptom management and designing a method appropriate for all demographic groups.

Studies have emphasized that emotional distress is a strong factor behind the battle with cervical cancer and patients reported a higher amount of anxiety and depression (Wenzel *et al.*, 2003). The assessment of HRQoL by Herzog and Wright (2007) found that anxiety, distress, and concern are high in women with cervical cancer. This anxiety and depression affect the HRQoL patients greatly (Coyne *et al.*, 2008; Khalil *et al.*, 2015). Depression and anxiety have been reported in multiple HRQoL studies similar to the current study which confirms the psychological status of women being treated for cervical cancer in Addis Ababa Ethiopia. The cultural inhibitions and the image of an illness could exaggerate the impact on the HRQoL of the patients (Xie *et al.*, 2013). As emotional distress is found to be a predictive factor for the HRQOL the health professionals could

help improve the HRQOL of patients by alleviating factors that bring about emotional distress and providing counseling.

In Addition to the factors mentioned above other studies have discussed that social support and sexual functioning only were predictive of the GQOL of patients (Gotay et al. 2008). Contrary to (Prasongvejet *et al.*, 2017, Torkzahrani, 2013), the current study did not find sexual activity predictive of GQOL of patients. Even though the sexual activity is almost close to nothing, it may not have been predictive due to the values that are given to sexual activity in comparison to the illness. However, studies confirm that ability to sexually function had a positive relationship with the physical, social and functional wellbeing thus with a positive GQoL (Bjelic *et al.*, 2012, Bae and Park, 2016, Plotti *et al.*, 2011).

The EQ-5D-5L instrument found that there is slight to moderate pain, slight mobility issues and slight anxiety and depression on the majority of the participants; pain was the major complaint. Similar to study done in Scotland described a comparable result of anxiety and depression with only 35% of patients reported no stress or worry about their disease (McKenzie and Van Der, 2009). Cervical cancer patients' utility score was also found to be 0.77 and this finding can be used as an input to perform cost utility analysis useful to generate evidence helpful to implement policy changes and improve patients' QoL (Kim, 2012; Paradowska *et al.*, 2014).

8. Strength and limitation

The strength of the study is the large sample size and the use of validated measurement tools. Despite the sample heterogeneity, the results indicate that the two QOL assessment tools were able to discriminate between groups of cervical cancer patients.

The validation study had certain limitations. The study was a cross-sectional that did not measure test–retest reliability and the responsiveness of the EORTC QLQ-CX24. The limited number of sexually active patients could not indicate the actual correlation of the scales thus; further research should be done in a larger sample size of sexually active women. In addition, our study is cross-sectional a without control group (e.g. healthy women).

9. Conclusion

The Amharic version of the EORTC QOQ CX 24 was proved to be patient-friendly and well accepted by patients with cervical cancer with a high completion rate and a low missing response rate of items. Finding of this study provide that the Amharic version of the EORTC QLQ-CX24 questionnaire can be used as acceptable, a reliable and efficient tool in clinical use and clinical research to study the HRQoL of cervical cancer in Ethiopia.

Cervical cancer patients reported poor HRQoL and above average utility score. Predictive factors for the GQoL were Physical functioning, Emotional functioning, and Pain and symptom experience Hence, Strong psychological support, Pain management and awareness creation including their care takers and partners should be included in the management of this patient group. Patients who have not received any treatment reported a lower quality of life. The utility score of 0.77 indicated that the patients prefer to stay 7 years in a normal heath state than 10 years in current health state.

10. Recommendations

Based on the findings of the study, the following recommendations have been made.

- The HRQoL of patients should be assessed deeply in terms of treatment protocols
- Psychological support should be considered as an additional care for patients with cervical cancer.
- Pain management should continue to be another area of focus as pain and symptom experience affect the GQoL.
- Treatments should be available readily as symptoms of cervical cancer severely affect the social functioning of patients.
- Further utility assessments should be done in order to identify proper interventions
- Follow up studies should be done to determine the HRQoL of patients and changes due to different factors.
- Qualitative studies should be incorporated in order to better understand the patients spiritual and emotional connections

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Annex

አዲስ አበባ ዩኒቨርሲቲ

ፋርማሲ ትምህርት ቤት እና ህክምና ትምህርት ቤት

ጥቁር አንበሳ ስፔሻላይዜድ ሆስፒታል ውስጥ በመታከም ላይ በሚገኙ የማህጸን ካንሰር ታማሚዎች ስለህመማቸው ሁኔታ መረጃለመስብሰብ የተዘጋጀ መጠይቅ፣2010 ዓ.ም

ተሳታፊዎች በጥናቱ ለመሳተፍ ፈቃደኝነታቸውን የሚገልፁበት ቅጽ

ጤና ይስጥልኝ እኔ _____ እባላለሁ በአሁኑ ወቅት በአዲስ አበባ ዩኒቨርሲቲ፣ ፊርማሲ ትምህርት ቤት ተማሪ ስሆን፣ ይህ ጥናት የማህጸን ካንሰር ላይ የሚሰራ የማስተርስ ጥናት ወረቀት ነው። በመሰራት ላይ ያለው ጥናት አላማ ስለ እርስዎ ጤንነትና ስለሚደረግልዎት ህክምና ለማጥናት ጠው። መጠይቁ ከጊዜዎ ቢበዛ 15 ደቂቃ የሚወስድ ሲሆን በዚህ ጥናት ውስጥ የእርስዎ ተሳታፊነት ሙሉ በሙሉ በእርስዎ ፈቃደኝነት ላይ የተመሰረተ ነው። በዚህ ጥናት ውስጥ ለመሳተፍም ሆነ ላለመሳተፍ መወሰንዎ በሆስፒታሉ ውስጥ በሚያገኙት አገልግሎት ላይ ምንም አይነት ተጽእኖ የማይኖረው ሲሆን ቃለ መጠይቁን በማንኛውም ሰዓት ማቋረጥ ወይም ጥያቄዎችን አለመመለስ ይችላሉ። በጥናቱ ውስጥ ለተነሱት ጥያቄዎች የሚሰጧቸው መልሶች ሙሉ በሙሉ በምስጢር የሚጠበቁ ሲሆን የእርስዎም ስም በማንኛውም መልኩ በጥናቱ ውስጥ አይገለጽም፤ እንዲሁም የሚሰጡት ምላሽ ከእርስዎ ማንነት ጋር በማንኛውም መልኩ አይያያዝም። በዚህ መጠይቅ ውስጥ ለቀረቡት ማንኛውም ጥያቄዎች ትክክለኛ ወይም የተሳሳቱ የሚባሉ ምላሾች የሉም። ዋናው የሚፈለገው በእነዚህ ጥያቄዎች ወይም አረፍተ ነገሮች ዙሪያ ያህዎት ምላሽ ነው።

በጥናቱ ለመሳተፍ ፈቃደኛነዎት?

አዎ አይደለሁም

- ፈቃደኛ መሆናቸውን ካረጋገጡ ቃለ መጠይቁን ይጀምሩ
- ፈቃደኛ ካልሆኑ ወደ ሚቀጥለው ተገልጋይ ይሸጋገሩ

• ክፍል አንድ-

<p>እርስዎን በተመለከተ አጠቃላይ መጠይቅ</p> <p>1.1. እድሜ _____ አመት</p> <p>1.2. ክልል _____</p> <p>1.3. ሀይማኖት _____</p> <p>1.4. የጋብቻ ሁኔታ</p>	<p>መልስ</p> <p>_____ አመት</p> <p>_____</p> <p>_____</p> <p>ያላገባችኋል <input type="checkbox"/> ባለትዳር <input type="checkbox"/></p> <p>አግብተው የፈቱ <input type="checkbox"/> የትዳር ዓደኛ ንበሞት ያጡ <input type="checkbox"/></p>
<p>1.5. የትምህርት ደረጃ</p>	<p>ማንበብና መጻፍ አልችልም <input type="checkbox"/></p> <p>ማንበብና መጻፍ እችላለሁ</p> <p>(መደበኛ ያሌሆነትም ህርት/የሃይማኖት ትምህርት) <input type="checkbox"/></p> <p>አንደኛ ደረጃ ትምህርት (ከ 1ኛ-8ኛ ክፍል) <input type="checkbox"/></p> <p>ሁለተኛ ደረጃ/መሰናዶ ትምህርት (ከ 9ኛ-12ኛ ክፍል) <input type="checkbox"/></p> <p>ከፍተኛ ትምህርት</p> <p>(ሰርተፍኬት፣ ዲፕሎማ፣ የመጀመሪያ ዲግሪና ከዚያ በላይ) <input type="checkbox"/></p>
<p>1.6. የስራ ቅጥር ሁኔታ</p> <p>1.7. ወርሃ አማካኝ የቤተሰብ ገቢ ብር</p>	<p>የመንግስት ሰራተኛ <input type="checkbox"/> የግሌ መሥሪያ ቤት ተቀጣሪ <input type="checkbox"/></p> <p>ነጋዴ <input type="checkbox"/> ጡረተኛ/ በጡረታ ከሥራ የተገለጹ <input type="checkbox"/></p> <p>አርሰ አደር <input type="checkbox"/> የቤት እመቤት <input type="checkbox"/> ሥራ አጥ <input type="checkbox"/></p> <p>ሌሎች፣ ይግለጹ _____</p> <p>_____</p>

Section 2: Medical Characteristics (to be filled through chart review by data collectors)

<p>2.1. Patient status</p>	<p>New patient <input type="checkbox"/> follow up <input type="checkbox"/></p>
<p>2.2. Time since diagnosis</p>	<p>_____</p>
<p>2.3. Stage of cancer</p>	<p>Stage I <input type="checkbox"/> Stage II <input type="checkbox"/></p> <p>Stage III <input type="checkbox"/> Stage IV <input type="checkbox"/></p> <p>If Not mentioned, please write the card number _____</p>

2.4. Treatment history	Surgery <input type="checkbox"/> chemotherapy only <input type="checkbox"/> radiation only <input type="checkbox"/>
2.5. Current type of anticancer treatment (within the period of the data collection) (more than one answer possible)	Surgery <input type="checkbox"/> chemotherapy only <input type="checkbox"/> radiation only <input type="checkbox"/>
2.6. Please specify known comorbid condition	_____



EORTC QLQ – CX24

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems, please answer by circling the number that best applies to you.

During the past week:	Not at all	A little	Quite a bit	Very much
31. Have you had cramps in your abdomen?	1	2	3	4
32. Have you had difficulty in controlling your bowels?	1	2	3	4
33. Have you had blood in your stools (motions)?	1	2	3	4
34. Did you pass water/urine frequently?	1	2	3	4
35. Have you had pain or a burning feeling when passing water/urinating?	1	2	3	4
36. Have you had leaking of urine?	1	2	3	4
37. Have you had difficulty emptying your bladder?	1	2	3	4
38. Have you had swelling in one or both legs?	1	2	3	4
39. Have you had pain in your lower back?	1	2	3	4
40. Have you had tingling or numbness in your hands or feet?	1	2	3	4
41. Have you had irritation or soreness in your vagina or vulva?	1	2	3	4
42. Have you had discharge from your vagina?	1	2	3	4
43. Have you had abnormal bleeding from your vagina?	1	2	3	4
44. Have you had hot flushes and/or sweats?	1	2	3	4
45. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
46. Have you felt less feminine as a result of your disease or treatment?	1	2	3	4
47. Have you felt dissatisfied with your body?	1	2	3	4

Please go on to the next page

During the past 4 weeks:

	Not at all	A little	Quite a bit	Very much
48. Have you worried that sex would be painful?	1	2	3	4
49. Have you been sexually active?	1	2	3	4

Answer these questions only if you have been sexually active during the past 4 weeks:

	Not at all	A little	Quite a bit	Very much
50. Has your vagina felt dry during sexual activity?	1	2	3	4
51. Has your vagina felt short?	1	2	3	4
52. Has your vagina felt tight?	1	2	3	4
53. Have you had pain during sexual intercourse or other sexual activity?	1	2	3	4
54. Was sexual activity enjoyable for you?	1	2	3	4

EORTC QLQ — CX24

አንዳንድ ታካሚዎቻችን የተለያዩ ምልክቶችና ስሜቶች እንደሚሰማቸው፡፡ እባክዎን ከስር የተጠቀሱትን ስሜቶች በምን ያህል ሁኔታ እንደተሰማዎት ይግለጹልኝ፡፡

ባለፉት ሳምንታት

	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
31. የሆድቁርጠት ስሜት ተሰምቶታል	1	2	3	4
32. የአንጅት እንቅስቃሴ መቆጣጠር ችግር አለ	1	2	3	4
33. ሰገራዎላይደም አይተው ያውቃሉ	1	2	3	4
34. ቶሎቶሎ ይሸናሉ	1	2	3	4
35. በሚሸኑ ጊዜ የህመም ስሜት አለው	1	2	3	4
36. የሽንት ውሃ አምልጥዎት ያውቃል	1	2	3	4
37. ሙሉ በሙሉ ከፍኛ የሽንት ውሃን ማስወገድ ያስቸግሮታል	1	2	3	4
38. አንደኛው ወይም ሁለቱ እግር ላይ እብጠት አይተዋል	1	2	3	4
39. የወገብ ህመም ተሰምቶት የውቃል	1	2	3	4
40. እግርዎ ላይ የመቆጥቆጥ ወይም የስሜት ማጣት ነገር አይተው ያውቃሉ	1	2	3	4
41. በማህፀንዎ አካባቢ የሚቃጠል ስሜት ተሰምቶት ያውቃል	1	2	3	4
42. ከማህፀንዎ ፈሳሽ ነገር ይዋጣል ነበር	1	2	3	4
43. ከማህፀንዎ ያልተለመደ ደም መድማት አጋጥሞታል	1	2	3	4
44. የሰውነት ሙቀት መጨመር ወይም ስብደት ጋጥሞታል	1	2	3	4
45. በህመምም ከንጹህ ስለሰውነት አካላት ያውቁት የቀነሰ ስሜት ይሰማዎታል	1	2	3	4
46. በህመምም ከንጹህ የሴትነት ስሜት ያቀንሷል	1	2	3	4

	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
47. ስለ አካላዊ ሁኔታዎ ያለ መርካት ስሜት ያጋጥሞታል	1	2	3	4
ባለፉት 4 ሳምንታት				
48. የግብረ ስጋ ግንኙነት የህመም ስሜት ያመጣብኛል ብለው አስበው ያውቃሉ	1	2	3	4
49. የግብረ ስጋ ግንኙነት አርገው ያውቃሉ	1	2	3	4

የሚከተሉትን ጥያቄዎች የሚመልሱት ላለፉት 4 ሳምንታት የግብረ ስጋ ግንኙነት ካደረጉ በቻነው፡፡

	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
50. በግንኙነት ጊዜ ማህፀንዎ የመድረቅ ስሜት ነበረው	1	2	3	4
51. ማህፀንዎ ያጠረ መስሎ ተሰምቶታል	1	2	3	4
52. ማህፀንዎ የጠበበ መስልዎታል	1	2	3	4
53. በግንኙነት ጊዜ ወይም ካለ ግብረ ስጋ ግንኙነት) በግንኙነት ሁኔታ ላይ ህመም ተሰምቶታል	1	2	3	4
54. ይህ ግንኙነት አዝናኝቶታል	1	2	3	4

የጤና መጠይቅ

የአማርኛ ትርጉም ለኢትዮጵያ

(Amharic version for Ethiopia)

በአያንዳንዱ ርዕስ ስር፣ እባክዎ ዛሬ ያለዎትን ጤንነት በተሻለ ሁኔታ የሚገልጸው አንድ ሰውን ላይ ምልክት ያድርጉ።

እንቅስቃሴ

የመራመድ ችግር የለብኝም

አነስተኛ የሆነ የመራመድ ችግር አለብኝ

መጠነ ጥንቃቄ የሆነ የመራመድ ችግር አለብኝ

ከባድ የሆነ የመራመድ ችግር አለብኝ

ምንም መራመድ አልቻልኩም

ራስን መንከባከብ

ለመታጠብ ምሆነ ለመልበስ ምንም ችግር የለብኝም

ለመታጠብ ምሆነ ለመልበስ አነስተኛ የሆነ ችግር አለብኝ

ለመታጠብ ምሆነ ለመልበስ መጠነ ጥንቃቄ ችግር አለብኝ

ለመታጠብ ምሆነ ለመልበስ ከፍተኛ የሆነ ችግር አለብኝ

ራሴ ለመታጠብ ምሆነ ለመልበስ አልቻልኩም

መደበኛ ተግባራት (ለምሳሌ፡- ስራ፣ ትምህርት፣ የቤት ስራ፣ ጥራ፣ ቤተሰብ ወይም የእረፍት ጊዜ ተግባራት)

መደበኛ ተግባራትን ያለ ምንም ችግር አከናውናለሁ

መደበኛ+ግባራቶቹን ለማከናወን አነስተኛ ችግር አለብኝ

መደበኛ+ግባራቶቹን ለማከናወን መጠነኛ ችግር አለብኝ

መደበኛ+ግባራቶቹን ለማከናወን ከፍተኛ ችግር አለብኝ

መደበኛ+ግባራቶቹን ለማከናወን አልቸልም

የሕመም ስሜት/ምቹት ማጣት

የሕመም ስሜት ምሆነ የምቹት ማጣት ስሜት የለኝም

አነስተኛ የሕመም ስሜት ወይም የምቹት ማጣት ስሜት አለኝ

መጠነኛ የሕመም ስሜት ወይም የምቹት ማጣት ስሜት አለኝ

ከባድ የሕመም ስሜት ወይም የምቹት ማጣት ስሜት አለኝ

የከፋ የሕመም ስሜት ወይም የምቹት ማጣት ስሜት አለኝ

ጭንቀት/ድብርት

ጭንቀት ምሆነ ድብርት የለብኝም

አነስተኛ ጭንቀት ወይም ድብርት አለብኝ

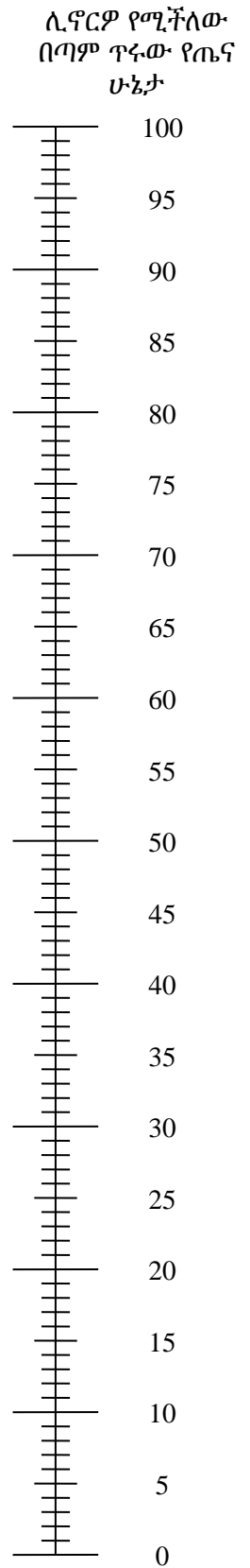
መጠነኛ ጭንቀት ወይም ድብርት አለብኝ

ከባድ ጭንቀት ወይም ድብርት አለብኝ

እጅግ ከባድ ጭንቀት ወይም ድብርት አለብኝ

- ዛሬ የጤና ሁኔታዎ ምን ያህል ጥሩ ወይም መጥፎ መሆኑን ለማወቅ እንፈልጋለን።
- መለኪያው ከ 0 እስከ 100 ድረስ ቁጥሮች አሉት።
- 100 ማለት ሊኖርዎ የሚችለው በጣም ጥሩ ወይም የጤና ሁኔታ ነው።
- 0 ማለት ሊኖርዎ የሚችለው በጣም መጥፎ ወይም የጤና ሁኔታ ነው።
- በመለኪያው ላይ ዛሬ ጤንነት ያለበትን ሁኔታ ለማሳየት የ X ምልክት ያድርጉ።
- አሁን፣ ከስርዓላው ሳጥን ውስጥ በመለኪያው ላይ ምልክት ያደረጉበትን ቁጥር ይጻፉ።

የዛሬ ጤንነትዎ =



ሊኖርዎ የሚችለው በጣም መጥፎው የጤና ሁኔታ

ECOG Performance Status

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or
5	Dead