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ASSESSING THE QUALITY OF LIFE AMONG PATIENTS WITH BREAST CANCER AT TIKUR ANBASSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA.

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Abstract

Background: Breast cancer is certainly the most common form of cancer among women in Ethiopia. For a long time the focus has been on clinical management of cancer but nowadays Quality of Life is emerging as an important health outcome which requires to be incorporated in the holistic management of patients. Breast cancer is becoming a major health problem in many developing countries such as Ethiopia. Even though the burden of breast cancer is increasing, there are no studies conducted in Ethiopia that have investigated QoL among breast cancer survivors.

Objective: The purpose of this study was to assess the quality of life of Ethiopian women with breast cancer who were patients at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia.

Methods: This study was an institutional based cross-sectional research conducted on 250 breast cancer patients from June to August, 2016. The Amharic version of European organization for research and treatment of cancer QoL questionnaires QLQ-C30 (Quality of Life Questionnaire-Cancer 30) and QLQ-BR23 (Quality of Life Questionnaire- Breast Cancer 23) were used to measure the quality of life. The data entered to EpiData 3.0 and then exported cleaned and analyzed using SPSS 20 version software. Multiple and binary logistic analysis was performed to examine the association between independent variables on QoL. Furthermore, analysis of variance (ANOVAs) and f-test was performed to examine the relationship between independent variables and functional and symptom scales of both questionnaires. Informed consent was obtained from the participants of the study.

Results: Overall, the results of this study are based on 250 respondents. On the EORTC-QLQ-C30, participants scored low quality of life (Mean =52.5; SD = 26.0). Functional scale scores ranged from a mean of 52.6 (SD=42.6) for role functioning to a mean of 74.1 (SD=28.59) for social functioning even though the items discriminatory ability was shown to be poor (α =0.32). Except for pain and appetite loss all symptoms scales received scores above 50 implying most of breast cancer patients were symptomatic. Like wises, among QLQ-BR23 scales, the best score was observed for future perspective (mean 82.1, SD 30.3)

which indicates that patients have had less worries about their future health. Most of the socio-demographic variables, except the level of income and age of participants, did not show significant association with QoL of the participants.

Conclusion: The quality of life among Ethiopian women with breast cancer is poor and measures should be taken to improve this.

Key words: Quality of life, breast cancer

Acknowledgement

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List of Abbreviations

ANOVA	Analysis of variance
BIS	Body Image Score
CF	Cognitive Functioning
CS	Chemo therapy and surgery
CT	Chemo Therapy
CSH	Chemo therapy, Surgery and Hormonal therapy
CSR	Chemo therapy, Surgery and Radiotherapy
EF	Emotional Functioning
ETB	Ethiopian Birr
EC	Ethiopian Calendar
EORTC	European Organization on Research and Treatment of Cancer
EORTC-QLQ-QLQ-C30	European Organization on Research and Treatment of Cancer, Quality of life questionnaire
EORTC-QLQ-BR23:	European Organization on Research and Treatment of Cancer, Quality of life questionnaire Breast Cancer Specific
HRQoL	Health Related Quality of Life
IAEA	International Atomic Energy Agency
IRB	Institutional review board
NA	Not Applicable
PF	Physical Functioning
QoL	Quality of Life
REK	Regionale Komiteer for Medisinskog Helsefaglig Forskningsetikk
RF	Role Functioning
RS	Raw Score
RT	Radiation Therapy
SD	Standard Deviation
SF	Social Functioning
SPSS	Statistical Package for the Social Sciences
TASRH	Tikur Anbassa Specialized Referral Hospital
USD	United States Dollar

1. INTRODUCTION

1.1. Background

Breast cancer is one of the most common health problems in the world. Annually, 1.3 million women are diagnosed with breast cancer worldwide which makes it the second most common form of cancer next to lung cancer worldwide (Michelle 2012). Different studies have shown that the number of patients with breast cancer is rising sharply in recent years. Breast cancer is the primary cause of death among women globally and it represents the most common female malignancy in both developing and developed countries (Benson and Jatoi 2012). Cancer has become one of the major health problems in Africa. Similar to the epidemiological transition, low-income and middle-income countries now face a cancer transition with infection-related and preventable cancers and an increase in previously less common cancers, such as breast cancer (Knaul 2011). Cancer and some other communicable diseases may overtake some infectious diseases as a leading cause of death by the year 2030 in the African region (WHO 2015). Currently, breast cancer is the most common cancer in Africa (Parkin et al. 2014). Moreover; it is reported to be the leading cause of cancer death in Africa (Parkin et al. 2014).

Ethiopia is one of the developing countries, which is a home to a growing population of more than 84 million people (Woldeamanuel, Girma, and Teklu 2013). Annually, around 60,000 new cases of breast cancer are diagnosed in Ethiopia (WHO 2015). The major obstacle in the country is the lack of trained health professionals such as oncologists and other health professionals (WHO 2015). In 2006, oncology service started in an organized way at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia. Tikur Anbassa Specialized Hospital is the only nation`s cancer referral center. This study will utilize this institution as a cross-sectional study to assess QoL of patients with breast cancer. A study which was designed to assess the pattern of cancer from 1998-2010 in Oncology center in Ethiopia showed that breast cancer was about 26% of the cases, which makes it the second most common malignancy in female next to gynecological malignancy (47%) (Tigeneh et al. 2015). Due to lack of awareness, breast cancer patients in Ethiopia often ignore lumps and usually seek

treatment only when symptoms such as pain and itching occur which can be a reason to poor prognosis (Woldeamanuel, Girma, and Teklu 2013). This, in turn, can lead to a deterioration of the quality of life of breast cancer patients.

The quality of life is a concept that came to focus after World War II and there have been many attempts at the definition of the concept (Poradzisz and Florczak 2013). The quality of life is defined as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (WHO 2016). The general well-being of individuals and societies has being evaluated by the term 'quality of life'(Heydarnejad, Hassanpour, and Solati 2011). Studies conducted on the quality of life in breast cancer patients made a huge contribution to improving breast cancer care (Montazeri 2008). Therefore, this research endeavors to bring insights on QoL of breast cancer patients at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia.

1.2. Problem Statement

Breast cancer is the second most prevalent cancer in African women next to cervical cancer (Obrist et al. 2014). Despite the rise in the prevalence of breast cancer, the survival rate of clients with breast cancer in most developed countries has been increasing recently which is believed to be due to earlier detection and improved treatment (Boehmer et al. 2012). However, the survival rate of clients with breast cancer in most low and middle-income countries are still relatively low (Omotara et al. 2012). About two-thirds of the annual cancer mortality and more than 50% of all new cancers worldwide happen in low income and middle-income countries (Knaul 2011). The incurable nature of breast cancer along with its reoccurrence causes psychological distress to clients than the diagnosis of primary breast cancer that in turn affects the quality of life of these patients (Perry, Kowalski, and Chang 2007, Grabsch et al. 2006).

During the search of literature, there is only a single published study in Ethiopia which encompasses QoL of cancer patients (Tadele 2015). The study used a quality of life scale

which was not specifically designed for breast cancer survivors but for measuring the quality of life in all cancer patients. Even though breast cancer is among the leading causes of morbidity and mortality among women, no report has been published that measures QoL specific to breast cancer patients in Ethiopia. Therefore, this study is probably the first study performed to measure the QoL among Ethiopian breast cancer patients using the QLQ-BR23 and QLQ-C30 instrument. Moreover, a better understanding of these variables may improve the design and evaluation of interventions and the integration of quality of life assessment during patient care.

1.3. Significance of the study

Studies suggest that QoL assessment is important to detect and treat physical or psychological manifestations. A study suggests that studies that assess QoL provide crucial information about the impact of a disease and its treatment on physical, functional, social and emotional well-being to the patients and health care providers (Lesley 2002). The quality of life measurements have become increasingly significant in different studies. Mainly, the measurements are becoming significant in various disciplines such as medicine, nursing, sociology and psychology (Salonen et al. 2011a). There has long been an agreement among clinicians and social scientists to use quality of life assessment to measure the outcome of medical intervention (Bowling 1995). Survival prediction, response to treatment and psychological morbidity screening in breast cancer clinical trials are being assessed by using quality of life measurement tools (Scott et al. 2008).

It is evident that breast cancer patients experience physical symptoms and psychological distress which can negatively affect their quality of life (Perry, Kowalski, and Chang 2007). The main purposes of different cancer treatments are improving the quality of life of clients either by cure or alleviating the adverse symptoms as much as possible (ibid). QoL assessment tools help to identify the influence of a disease and its treatments on various spheres of life of affected individuals (Kulesza-Bronczyk et al. 2014). Moreover, these tools can be used to guide a clinician about the patient's illness, design preventive measures and to

identify how certain treatments may affect the clients' QoL (Perry, Kowalski, and Chang 2007).

Since there is a scarcity of information about the quality of life and its associated factors among breast cancer women in Ethiopia, this study aims to assess the quality of life of Ethiopian women with breast cancer at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia. This study can be used by policy-makers and it can guide further research to improve QoL and treatment outcomes.

1.4 Literature review

1.4.1. Breast Cancer Morbidity and Mortality

Breast cancer is the most common malignancy which accounts almost 0.5 million deaths annually in the world (Benson and Jatoi 2012). Over the past three decades, the prevalence of breast cancer has increased and its number has almost doubled (Benson and Jatoi 2012). The risk of acquiring breast cancer increases as increased age and every woman in any age range are at risk of breast cancer (Omotara et al. 2012).

Evidence suggest that as we compare it to the previous times, the survival rates for breast cancer patients has improved over the decades in the developed world (Benson and Jatoi 2012). Among women who had breast cancer only 35% would be alive after ten years in the 1960s; however, this figure was changed to 77% by the mid-1980s (Michelle 2012). In the developed countries, early detection through the use of various advanced treatment options can be accredited for much of the recent improvement in outcome for women with breast cancer (Shulman et al. 2010). In comparison to other cancer types, breast cancer even with the presence of metastases has a long course of illness than other common cancers (Grabsch et al. 2006). The recognition of the incurable nature is of the disease with reoccurrence is associated with greater distress for many clients than the diagnosis of primary cancer (Perry, Kowalski, and Chang 2007).

Despite a higher prevalence in wealthier countries, the incidence of breast cancer is rising steadily in less affluent societies. The countries that had a moderate incidence rate in the past such as Eastern Europe, South America, southern Africa and Asia or those countries that had a low incidence rate in sub-Saharan Africa are now experiencing rapid increase in the incidence (Benson and Jatoi 2012). When we look at the rate of change of the breast cancer at risk population of a typical African country, Nigeria, the size of the at-risk population is increasing steeply than that of the developed country such as France (Ogundiran, Akarolo-Anthony, and Adebamowo 2010). Most African countries at this time have cone-shaped population pyramids which reflect a high fertility rate. Therefore, the majority of citizens of Africa are children and young adults and there are only small aging populations. When we look at the prevalence of breast cancer in African clinics, breast cancer among young women encompasses a higher proportion of the cases than among older women since African population has a low median age (Ogundiran, Akarolo-Anthony, and Adebamowo 2010). In contrast with older women, young breast cancer patients has a tendency to have clinically and pathologically aggressive breast cancer with rapid progression and a higher mortality in any population (ibid). Therefore, since African breast cancer patients tend to be young, the pattern of breast cancer that presents to clinics are mostly aggressive in the clinical course which is considered to have a high fatality rate (Ogundiran, Akarolo-Anthony, and Adebamowo 2010). Ethiopia is one of the developing countries with a cone-shaped population pyramid. Ethiopia is one of the developing countries with a high prevalence of breast carcinoma next to gynecological malignancy (Tigeneh et al. 2015). Moreover, the number of death due to breast cancer is increasing in the country (ibid).

1.4.2. Quality of life of patients' with breast cancer

For this particular study QoL among breast cancer clients should be understood as the perception of the clients about their physical, psychological, and social functioning following the diagnosis and treatment of the disease. QoL of patients with breast cancer is investigated in different studies mainly in the developed countries; however, there is a knowledge gap concerning the relationship between breast cancer and QoL of patients in Africa.

The influence of a disease and its treatments on various spheres of life of affected individuals can be investigated by QoL scores (Kulesza-Bronczyk et al. 2014). The EORTC QOQ-C30 is

a tool that is currently being used to assess the quality of life of patients with cancer. This tool has a possible mean range between 0-100 with the scores for global health status which with high score represents better QoL (Aaronson et al. 1993). This tool incorporates different items which investigate the different dimensions of QoL in cancer patients such as functional, symptom, a global health status/QoL scale and different symptoms commonly reported by cancer patients. Moreover, breast cancer-related symptoms are being investigated using the QLQ-BR23 questionnaire in addition to the core questionnaire to assess the quality of life for breast cancer patients.

Therefore, different studies conducted to assess QoL of patients with breast cancer by using these tools (EORTC QOQ-C30 and QLQ-BR23) reported different scores of different scales. According to these tools, a study conducted in Iran showed a low global health status among breast cancer patients which indicates low QoL (Safaee et al. 2008). This means that those breast cancer patients who were investigated in the study had low QoL. Low global health score is also reported among women with advanced breast cancer in a cross-sectional study conducted in Australia (Grabsch et al. 2006). This implied that the study participants had low QoL.

According to EORTC QOQ-C30, a high functional scale score represents a high/healthy level of functioning (Aaronson et al. 1993). The best functional outcomes (high level of functioning) were found for the cognitive and social functioning subscales among breast cancer patients who were admitted and treated in chemotherapy ward of Namazi hospital, south of Iran (Safaee et al. 2008). However, the same study showed low emotional functioning among the participants of the study (Safaee et al. 2008). In addition to cancer-related symptoms, breast cancer patients may experience an acute side effect of the treatment which can be emotionally distressing and debilitating which in turn may affect their QoL (ibid). Different studies show that clients with breast cancer can experience impaired body image and sexual health due to changed anatomy, loss of function and poor cosmesis related with breast cancer and its treatment (Kinamore 2008).

1.4.3. Factors associated with quality of life of patient's with breast cancer

Studies show that different factors can alter the health-related quality of life (HRQoL) of breast cancer survivors (Moro-Valdezate et al. 2014). A study conducted in Bahrain revealed that breast cancer patients who had high income, were premenopausal, were not married and had no history of metastases tended to have better global health-related quality of life (Jassim and Whitford 2013). Monthly family income less than 100 USD was associated with poor social functioning among Nepalese breast cancer patients (Manandhar et al. 2014). Moreover, the level of education, occupation, household income and type of health insurance were significantly associated with QoL of Chinese breast cancer patients (Yan et al. 2016). Which imply that social support and financial aid can improve patients QoL. An association between level of employment and body image reported; as employed women with breast cancer in Finland had a smaller risk of negative changes in body image than retired women (Salonen et al. 2011e). Mean sexual functioning and sexual enjoyment scores were higher for women< 50 years old when compared to women >50 years old among UK breast cancer survivors (Hopwood et al. 2008).

Some studies showed that time after treatments has an association with QoL of breast cancer patients. As reported by a study done in Sweden, time since diagnosis tended to have an association with HRQoL thus, breast cancer patients reported improved HRQoL over time (Larsson, Sandelin, and Forsberg 2010). Furthermore, a study done in Poland showed that QoL among breast cancer patients surveyed one year after mastectomy turned out to be significantly higher than in those examined one month after surgery (Kulesza-Bronczyk et al. 2014). A study conducted in Bahrain showed that breast cancer patients who were recently diagnosed were more worried about their future, complained of more symptoms and more upset by the loss of hair (Jassim and Whitford 2013).

Some studies reviled that there is a significant association between type of treatments and QoL in breast cancer patients. For example, a study conducted in Iraq describes this association in which breast cancer patients who took chemotherapy had medium impairment of QoL regarding physical problems while those who took radiotherapy had bad effects on their QoL (Alzabaidey 2012). However, Chinese breast cancer patients who received

chemotherapy reported lower scores for QoL (Yan et al. 2016). Among Indian breast cancer patients, those who had mastectomy had a better sexual functioning and sexual enjoyment as compared to those who had breast conservation therapy (Dubashi et al. 2010). On the other hand, physical health was similar across mastectomy group compared to breast conservation group among Indian breast cancer patients (Dubashi et al. 2010). Distress due to hair loss was seen to be significantly associated with chemotherapy, type of surgery and age (Hopwood et al. 2008). More intense upset by hair loss was noted among breast cancer patients who were recently diagnosed, divorced as opposed to single women and those who had intermediate education in Bahrain (Jassim and Whitford 2013). Jassim and Whitford (2013) further reported that advanced staging, metastases and shorter time since diagnosis had a major effect on QoL of breast cancer patients. The evidence above shows that QoL of breast cancer patients researched in different parts of the world produced different results. Several factors have been identified, therefore, it would be interesting to investigate the association between the experience of breast cancer, socio-demographic characteristics and QoL among Ethiopian women with breast cancer.

2. OBJECTIVE

2.1. General Objective

The purpose of this study was to assess the quality of life of Ethiopian women with breast cancer who were patients at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia.

2.2. Specific Objectives

1. To describe the quality of life of Ethiopian women with breast cancer at Tikur Anbassa Specialized Hospital.

2. To assess the association between socio-demographic characteristics and quality of life of Ethiopian women with breast cancer.

3. To assess the association between type of treatment and quality of life of Ethiopian women with breast cancer

4. To assess the association between duration of treatment and quality of life of Ethiopian women with breast cancer

Research Questions

The following research question will be addressed in this study.

What is the association between the experience of breast cancer, socio-demographic characteristics and QoL among Ethiopian women with breast cancer?

3. METHOD OF DATA ANALYSIS

3.1. Questionnaires

3.1.1. Socio-demographic and clinical Characteristics

The questionnaire included socio-demographic characteristics such as age (in years), marital status, educational status, occupation and monthly income (in birr). Moreover, it includes the clinical characteristics such as time since diagnosis and type of therapy they have taken.

3.1.2. Quality of life

In addition to a questionnaire containing socio-demographic characteristics and type and duration of treatment, the European Organization for Research and Treatment of Cancer (EORTC) version 3.0 of QLQ-C30 questionnaire was used to examine the QoL. Moreover, QoL breast cancer specific version (EORTC QLQ-BR23) questionnaire was used to assess breast cancer specific predictors of QoL. Therefore, the total of 60 items were incorporated in the questionnaire which includes the QLQ-C30 (30 items), EORTC QLQ-BR23 (23 items) and socio-demographic characteristics, type and duration of treatment (7 items) questions.

The data was collected using the Amharic version of EORTC QLQ-C30 and EORTC QLQ-BR23 questionnaire in addition to the basic background socio-demographic and clinical characteristics questions. The EORTC is an organization that has a set of a standardized questioners targeted to assess the QoL of cancer patients in general and different supplementary modules targeted for specific cancer types such as breast cancer (WHOQOLGROUP 1998). The QLQ-C30 is the main questionnaire which is aimed to address health-related quality of life of cancer patients in general. It incorporates 30 items among which are nine multi-item scales: five functional scales (Physical, Role, Cognitive, Emotional and Social Functioning); three symptom scales (Fatigue, Pain and Nausea or Vomiting), a global health status / QoL scale, and a number of single items assessing additional symptoms commonly reported by cancer patients (dyspnoea, loss of appetite,

insomnia, constipation and diarrhoea) and perceived financial impact of the disease. While the QLQ-BR23, which assesses the quality of life for breast cancer patients, has 23 items assessing disease symptoms, side effects of treatment (surgery, chemotherapy, radiotherapy and hormonal treatment), body image, sexual functioning and future perspective to predict the specific breast cancer related QoL predictors (Aaronson et al. 1993). Therefore, the 53 questions from EORTC (30 questions QLQ-C30 and 23 questions QLQ-BR23) in addition to the 7 socio-demographic and clinical characteristics questions were used to collect data from the study participants in this study.

The participants of the study requested to select only one answer from (''1- Not at all, 2- A little, 3- Quite a bit or 4- Very much'') for the first 28 questions and they were asked to select one between the range from 1 (which means Very poor) to 7 (Excellent) in the EORTC QLQ-C30 items global health status questions. When it comes to EORTC QLQ-BR23 questions, the participants requested to select only one answer (''1-Not at all, 2-A little, 3-Quite a bit or 4-Very much'') for each question.

3.2 Scoring procedure (Statistical analysis)

A supplemental scoring manual is provided with the questionnaire which was followed in the analysis. The QLQ-C30 is composed of both multi-item scales and single-item measures. These include five functional scales, three symptom scales, a global health status / QoL scale, and six single items. Each of the multi-item scales includes a different set of items - no item occurs in more than one scale. All of the scales and single-item measures range in score from 0 to100. Range is the difference between the maximum possible value of Raw Scores (RS) and the minimum possible value. The QLQ-C30 has been designed so that all items in any scale take the same range of values. Therefore, the range of RS equals the range of the item values. Most items are scored 1 to 4, giving range = 3. The exceptions are the items contributing to the global health status / QoL, which are 7-point questions with range = 6 (Aaronson et al. 1993) .

A high scale score represents a higher response level. Thus a

➤ **High score for a functional scale** represents a high / healthy level of functioning

➤ **High score for the global health status / QoL** represents a high QoL, but

➤ **A high score for a symptom scale / item** represents a high level of symptomatology / problems.

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

1. Estimate the average of the items that contribute to the scale; this is the raw score.

2. Use a linear transformation to standardize the raw score, so that scores range from 0 to 100; a higher score represents a higher ("better") level of functioning, or a higher ("worse") level of symptoms.

In practical terms, if items I1, I2, ... In are included in a scale, the procedure is as follows:

Raw score

Calculate the raw score

Raw Score = RS = (I1 + I2 +...+ In)/ n

Linear transformation

Apply the linear transformation to 0-100 to obtain the score S,

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

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

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

Range is the difference between the maximum possible value of RS and the minimum possible value. The QLQ-C30 has been designed so that all items in any scale take the same range of values. Therefore, the range of RS equals the range of the item values. Most items are scored 1 to 4, giving range = 3. The exceptions are the items contributing to the global health status / QoL, which are 7-point questions with range = 6 (Aaronson et al. 1993).

Similar questions were analyzed together for both questionnaires as presented in the tables 1 and 2 below.

Table 1 Scoring of items in EORTC QLQ-C30 V3with their analysis categories

Analysis Category	Scale	Number of items	Item range	Question numbers analyzed together
Global health status/QoL				
Global health status/QoL	QL	2	6	29,30
Functional scales				
Physical functioning	PF	5	3	1 to 5
Role functioning	RF	2	3	6 and 7
Emotional functioning	EF	4	3	21 to 24
Cognitive functioning	CF	2	3	20 and 25
Social functioning	SF	3	3	26 and 27
Symptom scales/items				
Fatigue	FA	3	3	10,12 and 18
Nausea and Vomiting	NV	2	3	14 and 15
Pain	PA	2	3	9 and 19
Dyspnea	DY	1	3	8
Insomnia	SL	1	3	11
Appetite loss	AP	1	3	13
Constipation	CO	1	3	16
Diarrhea	DI	1	3	17
Financial difficulties	FI	1	3	28

* Item range is the difference between the possible maximum and the minimum response to individual items; most items take values from 1 to 4, giving range = 3

Table 2: Scoring of items in EORTC QLQ-BR23 with their analysis categories

	Scale name	Number of items	Item range*	QLQ-BR23 item number
Functional scales				
Body image	BRBI	4	3	9-12
Sexual functioning†	BRSEF	2	3	14,15
Sexual enjoyment†	BRSEE	1	3	16
Future perspective	BRFU	1	3	13
Symptom scales / items				
Systemic therapy side effects	BRST	7	3	1-4,6,7,8
Breast symptoms	BRBS	4	3	20-23
Arm symptoms	BRAS	3	3	17,18,19
Upset by hair loss	BRHL	1	3	5

Remarks

1. Sexual enjoyment (BRSEE) is not applicable if item 15 is scored "not at all."

2. Upset by hair loss (BRHL) is not applicable if item 4 is "not at all."

* "Item range" is the difference between the possible maximum and the minimum response to individual items.

† Items for the scales marked † are scored positively (i.e. "very much" is best) and therefore use the same algebraic equation as for symptom scales; however, the Body Image scale uses the algebraic equation for functioning scales (Aaronson et al. 1993).

In this study, the raw scores for both EORTC QLQ-C30 and EORTC QLQ-BR23 were transformed to scores ranging from 0 to 100. There are no clear threshold levels stated in the search of literatures and in the scoring manuals for the EORTC QLQ-C30 and EORTC QLQ-BR23 scales to indicate the threshold scores that are likely to mean significant impairment. Therefore, in this study, after transformation of each domain, it was dichotomized into "Affected at any degree" and "Not affected at all". In which a score below 75 (above 75 mean no problem at all) for functional and QoL scales which indicate affected domain at any degree are used as affected. Scores above 25 mean (below 25 indicates no symptom at all)

which indicate there was a problem at any degrees have been used as affected for symptom scales.

3.3 Statistical analysis

The data was entered into EpiData 3.0 and then exported to the Statistical Package for Social Sciences (SPSS) version 20.0 for further cleaning and analysis. Before analyzing the surveys, responses were reverse coded as appropriate. Simple descriptive statistics such as frequencies, means, and standard deviations (SD) were calculated as appropriate. The internal consistency of the questionnaires was assessed by estimating the Cronbach's alpha (α) values of the multi-item scales based on the recommendation of $\alpha > 0.70$.

Missing values were treated according to the scoring manual, which allows up to 50% missing observations per score. This means that the patient had to answer at least half of the items on the scale. In addition, the single-item measures were transformed into the same percentile scale. The transformation from raw score to percentile scale allowed the author to run a more sophisticated analysis of the data.

Mean scores and mean differences of EORTC- QLQ-C30 and EORTC- QLQ-BR23 were calculated. After QoL, symptom and functional scales have been dichotomized bivariate and multivariate logistic regression analyses were used to explore the association between age, marital status, educational status, average monthly income, type of anti-cancer treatment, time since diagnosis and QoL and the possible association between functional and symptom scales with QoL. Crude and adjusted odds ratio (COR and AOR) at 95% level of confidence were calculated. One way analysis of variance (ANOVA) was performed to see if there were a significant mean difference between the different scale groups and socio-demographic variables which include age, marital status, income, educational status and occupation and time since diagnosis and type of anti-cancer treatment was included from clinical characteristics. For those scales with more than one item, the internal consistency of the instrument was assessed by calculating the Cronbach's alpha coefficient. A higher value of Cronbach's alpha ($\alpha > 0.7$) generally shows reliable internal consistency. While lower values ($\alpha < 0.7$) may indicate questionable internal consistency.

4. MATERIAL AND METHODOLOGY

4.1 Study Area and Period

This study was conducted at Tikur Anbassa Specialized Referral Hospital (TASRH) oncology unit from June- August 2016.

Tiruk Anbassa Specialized Referral Hospital is government owned large referral teaching hospital, located in Kirkos sub-city under the administration of Addis Ababa University, College of Health sciences. Addis Ababa is a capital city of Ethiopia. The hospital has been inaugurated by the title "Prince Mokonnen the Duke of Harar" Memorial Hospital on 3/11/1973 and merged with the princess Tsehay memorial Hospital on 24/5/1975 by the name of Tikur Anbassa Hospital.

The oncology center at the Hospital is the only referral center in the country. The hospital has 600 beds, of which 18 are allocated to cancer treatment. Of the 201 physicians at the hospital, only two are hematologists, four are medical oncologists, four are radiotherapists, two are surgical oncologists, and one is a pediatric oncologist. Three palliative pain specialists also work at the hospital. Only 26 of the Black Lion's 627 nurses are dedicated oncology nurses. The hospital has one CT scanner and one MRI scanner. In 2010, more than 260 000 patients in total were treated in the hospital, including more than 2000 adults and more than 200 children with cancer. Treatments offered at the Black Lion Hospital cancer center include anti-cancer drugs, surgery, and radiotherapy (Woldeamanuel, Girma, and Teklu 2013).

The Tele Therapy (commonly known as radiotherapy) center which is located and part of Tikur Anbassa Hospital. The hospital is the only institution which provides radiotherapy in Ethiopia. The radiotherapy center is opened in 1997 and it is a joint project between the Ethiopian government and the International Atomic Energy Agency (IAEA). In its first four years, the facility has treated 1,300 patients, with the number of patients growing steadily. Though a complete and recent data is not available, until 2009 there is a record of treatment provision for 11,983 patients who came from all regions in the country.

4.2. Study Design

Institution based cross-sectional research design was employed in this study.

4.3. Source and Study Population

All breast cancer patients being evaluated and treated at the outpatient in oncology units were considered as a source population. Those breast cancer patients visiting the hospital and being evaluated or treated at the units from June-August/2016 and who met the eligibility criteria were invited as a study population.

4.4. Inclusion and Exclusion criteria

4.4.1. Inclusion criteria
All out-patient female breast cancer patients who visited the hospital during the data collection period were eligible for participation in the study.

4.4.2 Exclusion criterion
Mentally incompetent patients, male breast cancer patients and other cancer patients (other than breast cancer) were excluded from the study.

4.5. Sampling

4.5.1. Sample size
The data was collected from June-August 2016 from all the breast cancer patients who fulfilled the inclusion criteria. Convenience sampling method was used. Therefore, 250 breast cancer patients who visited the hospital during the data collection period, who fulfilled the criteria and were willing to participate in the study, were included.

4.6 Study Variables

4.6.1. Dependent variables
- Quality of life

4.6.2. Independent variables

- Socio-demographic characteristics such as age (in years), marital status, educational status, occupation and average monthly income (in birr)

- Clinical characteristics such as duration of time since diagnosis and type of anticancer treatment

4.7 Data collection

The data were collected through an interview with participants in a private meeting room at TASRH oncology unit. Patients who fulfilled the criteria were interviewed in the study. Each participant was individually interviewed after explaining the purpose of the study and obtaining an informed consent for participation in the study.

4.8. Data Quality Management

The questionnaire was piloted on 38 female breast cancer patients who were illegible in the same hospital before the study period to identify the clarity and applicability of the tools, and to provide feedback about the questionnaire and standardize the data collection approach.

4.9. Ethical considerations

This study was conducted through a direct interview of breast cancer patients. Therefore, ethical issues were considered in collecting, analyzing and reporting of the data. Permission letters were obtained from EORTC research group to use questionnaire and Tikur Anbassa specialized referral hospital to collect the data. The nurses and doctors at the oncology department were informed about the objective of the study and requested to inform the patients about the study and ask them if they were willing to participate. All participants gave an informed consent before they meet the data collector for an interview. For those participants who could not read and write, oral consent was asked and given. Furthermore, the data collector read the information letter to those who could read if they wanted before they signed the informed consent. Ethical clearance and professional approval was obtained from Regionale Komiteer for Medisinskog Helsefaglig Forskningsetikk (REK) and Institutional review board (IRB) of the College of Health Sciences of Addis Ababa University.

4.10. Dissemination of Results

The result of this study will be submitted to Oslo and Akershus University College of Applied Sciences and TASRH at Addis Ababa University, College of Health Sciences and the copies will be given to TASRH oncology unit. The findings will also be attempted to be published in local or international journals and presentations at scientific conferences.

5. RESULTS

The results of this research were based on 250 participants of the study who successfully completed the interview.

5.1. Socio-demographic Characteristics

The participants mean age was 45.51 ± 11.18 years (Mean ± SD). Most of the participants were married 160 (64.4%) followed by divorced 39 (15.6%). The majority of the respondents 173 (69.2%) had completed some level of formal education while the rest 77 (30.8%) of the respondents didn't attended formal education. More than half of the respondent 142 (56.8%) were housewives. The remaining participant had some sort of income source. Only 37.6% of the respondent earned more than >701 ETB (Ethiopian Birr) (Table 3 below summarizes the socio demographic characteristics of respondents).

Table 3 Socio-demographic characteristics of breast cancer patients at TASRH, June – September 2016, Addis Ababa, Ethiopia

Variable	Frequency N = 250	Percent
Age in completed year (Mean 45.51 ± SD 11.18)		
<40	102	40.8
40-49	53	21.2
50-59	63	25.2
>=60	32	12.8
Marital Status		
Never married	22	8.8
Married	160	64.0
Widowed	29	11.6
Divorced	39	15.6
Educational level		
No formal education	77	30.8
<=6th grade	43	17.2

7th to 9th grade	33	13.2
10th to 12th grade	31	12.4
12th grade and above	66	26.4
Occupation		
Housewife	142	56.8
Government employee	57	22.8
Merchant	26	10.4
Other*	25	10.0
Average monthly income in ETB		
No income	75	30.0
<320	41	16.4
320-700	40	16.0
>701	94	37.6

*Retired, student, farming, private employee

5.2 Clinical characteristics

The study participants were diagnosed with breast cancer and were under treatment for a period of time ranging from less than 12 months up to more than or equal to 60 months. The mean length of time since the diagnosis of breast cancer was 40.7 months (3.4 years), (Mean 40.7 ±SD 33.9; range 3 to 216 months) and 5 years elapsed since the first diagnosis of breast cancer among 23.6% of respondents. Most of the participants (96.8%) received treatment in the form of chemotherapy alone or in combination with other forms of treatment such as surgery, radiotherapy, or hormonally therap. The majority of the participants (52.4%) received combination treatment of chemotherapy with surgery (Figures 1 and 2).
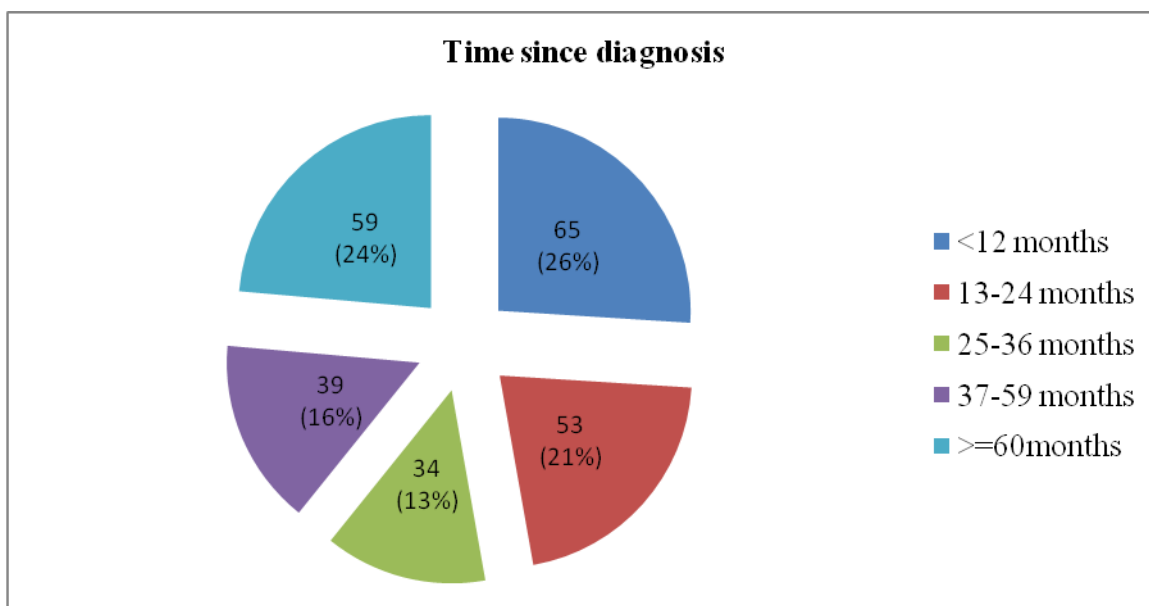
Figure 1 Duration of disease diagnosis (time since diagnosis) of breast cancer patients at TASRH, June – September 2016, Addis Ababa, Ethiopia
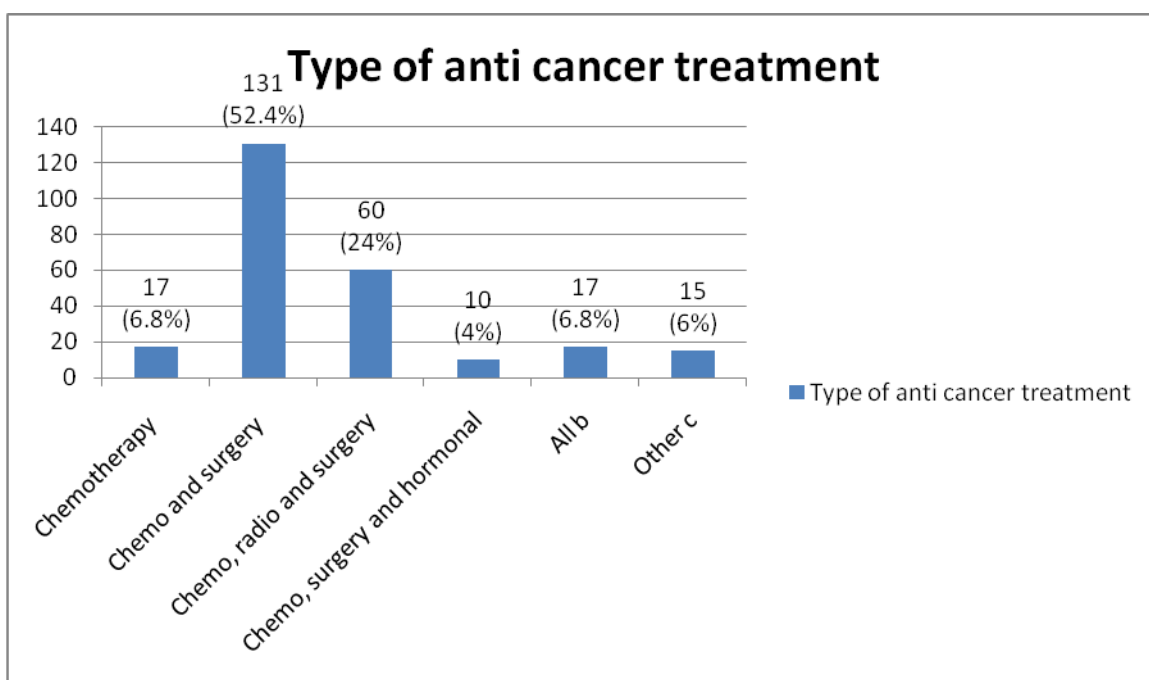
[b] Combination of Chemotherapy, Radiotherapy, Surgery and Hormonal therapy

[c] Surgery only (1),Hormonal therapy only(5),Chemo and Radiotherapy (7),Radio therapy and surgery(1) and surgery and hormonal therapy(1)

Figure 2 Type of anti-cancer treatment among breast cancer patients at TASRH, June – September 2016, Addis Ababa, Ethiopia

5.3. Quality of life among Ethiopian breast cancer patients

The participants scored a global health status/QOL scale with a (Mean =52.5; SD = 26.0). Functional scale scores ranged from a mean of 52.6 (SD=42.6) for role functioning to a mean of 74.1 (SD=28.59) for social functioning even though the items discriminatory ability was shown to be poor (α =0.32) (Table 4). Except for pain (mean 46.0) and appetite loss (mean 17.9) all the other symptom scales scored above the mean of 50.

On the other hand, in the QLQ-BR23 functioning scales/items, the best score was observed for future perspective (mean 82.1, ±SD 30.3). Patients also had a low mean score (29.0) for sexual functioning. When it comes to the symptom scales, the breast symptoms were fairly high with a mean score of 59.2 (table 4 below summarizes the mean score, SD and Cronbach's alpha).

Table 4: Means, standard deviations (SD) and Cronbach's Alpha values of the QLQ-C30 and QLQ-BR23 Scales Variables

Scale	Scales	Mean ±SD	Cronbach's alpha
QOL	Global health status /QOL	52.5±26.0	0.81
EORTC-QLQ-	**Functional scales**		
	Physical functioning	62.3±34.2	0.91
	Role functioning	52.6±42.6	0.94
	Emotional functioning	56.2±30.9	0.78
	Cognitive functioning	61.8±33.2	0.60
	Social functioning	74.1±28.5	0.32
	Symptom scales		
	Fatigue	50.0±27.6	0.51
	Nausea and vomiting	55.7±38.3	0.87
	Pain	46.0±31.9	0.40

	Dyspnea	57.1±41.5	NA
	Insomnia	53.5±42.1	NA
	Appetite loss	17.9±30.3	NA
	Constipation	62.5±35.7	NA
	Diarrhea	62.9±35.9	NA
	Financial difficulties	80.8±30.0	NA
QLQ-BR23	**Functional scales**		
	Body image	45.3±34.2	0.82
	Sexual functioning	29.0±26.2	0.1
	Sexual enjoyment	51.3±26.4	NA
	Future perspective	82.1±30.3	NA
	Symptom scales / items		
	Systemic therapy side effects	34.6±29.7	0.89
	Breast Symptoms	59.2±29.4	0.77
	Arm Symptoms	33.6±28.3	0.63
	Upset by Hair Loss	28.8±33.0	NA

NA: Not applicable (Reliability analysis is not applicable for a single item scales)

5.4 Mean differences between Socio-demographic and clinical variables with EORTC QLQ-C30 function scale

There was no significant mean difference across the age group, marital status, educational status, duration of disease and type of therapy with QOL score and all functional scales when measured with ANOVA. However, there was significant mean difference with monthly income in which those who were earning 320-700 ETB scored the lowest mean (poorest functioning) on physical and emotional functioning (Table 5 summarizes comparison between Socio-demographic and clinical variable and EORTC- QLQ-C30 functional scales).

Table 5: Mean differences between Socio-demographic variable and EORTC- QLQ-C30 functioning scales

Variable	QOL (Mean±SD)	PF (Mean±SD)	RF (Mean±SD)	EF (Mean±SD)	CF (Mean±SD)	SF (Mean±SD)
Age in completed year						
<40	50.3±26.7	61.6±35.8	53.6±44.4	55.3±31.0	61.4±34.1	73.2±30.0
40-49	53.3±23.6	68.4±29.6	58.8±42.9	52.7±32.3	61.3±33.6	70.8±29.6
50-59	53.7±28.2	56.1±35.0	49.2±39.2	58.7±30.3	63.2±33.2	75.4±26.6
>=60	55.7±23.1	66.3±35.0	45.8±42.8	59.6±29.9	60.9±30.7	79.7±25.7
P	0.709	0.236	0.498	0.663	0.984	0.536
Marital status						
Single	48.5±25.8	56.7±26.7	41.7±40.4	45.8±30.6	64.4±22.6	68.9±31.8
Married	51.6±26.5	62.0±36.1	53.3±43.9	57.3±31.3	59.5±34.9	72.7±29.0
Widowed	53.7±24.2	63.0±35.3	56.3±43.3	58.9±32.5	67.2±32.6	82.2±25.2
Divorced	57.5±25.6	65.8±29.0	53.0±37.8	55.1±27.6	65.8±31.5	76.5±26.1
P	0.533	0.796	0.634	0.398	0.522	0.295
Educational level						
No education	52.6±23.8	60.8±33.7	50.9±41.0	54.5±31.0	59.5±32.8	76.0±27.0
<=6th grade	57.2±25.9	67.3±33.9	60.9±42.4	63.4±29.3	69.4±31.3	81.0±28.3
7th to 9th	48.0±32.9	63.0±34.6	51.5±44.4	49.7±32.6	59.1±35.6	67.2±29.3
10th to 12th	47.3±24.1	56.6±35.4	43.0±42.3	51.9±29.6	61.3±34.0	68.3±33.7
12th & above	54.0±25.5	63.0±34.6	54.3±43.9	58.6±31.1	61.1±33.5	73.5±26.8

P	0.428	0.741	0.490	0.290	0.585	0.189
Occupation						
Housewife	54.3±25.5	63.4±33.7	53.1±42.6	56.4±32.3	62.8±33.1	75.8±27.8
Gov't employee	51.5±25.2	60.6±36.0	48.5±44.0	55.6±30.8	60.8±34.9	70.2±31.0
Merchant	52.9±29.1	63.1±34.5	67.9±41.1	62.8±27.4	66.0±31.8	80.8±23.9
Other[a]	44.0±26.8	58.9±33.5	43.3±38.5	49.3±25.8	54.0±32.	66.0±29.8
P	0.324	0.911	0.165	0.484	0.579	0.169
Average monthly income in ETB						
No income	56.6±25.5	67.7±33.4	53.6±43.5	57.8±32.4	62.7±33.9	74.9±29.3
<320	55.1±24.4	69.8±29.8	52.8±41.3	58.9±26.7	69.5±29.6	77.6±30.2
320-700	43.5±28.8	50.3±33.7*	45.8±43.2	41.7±31.7*	50.0±33.8	70.8±26.9
>700	52.0±25.3	59.7±35.5	54.6±42.5	59.8±29.6	62.8±33.1	73.2±28.0
P	0.070	0.025	0.741	0.013	0.059	0.730
Duration of disease (Time since diagnosis in months)						
<12	49.6±26.4	56.2±35.4	52.3±43.0	56.5±31.0	57.2±33.2	73.3±28.1
13-24	53.1±27.7	63.8±34.4	54.1±41.7	53.9±31.1	63.2±30.9	78.6±27.0
25-36	58.1±20.3	71.6±28.1	52.0±41.6	62.3±28.5	62.3±30.8	74.5±28.5
37-59	51.5±27.4	59.3±34.2	48.7±42.1	56.0±29.0	64.1±33.2	73.9±25.9
>=60	52.5±26.2	64.2±35.3	54.5±44.9	54.4±33.5	63.8±36.9	70.6±32.1
P	0.654	0.273	0.972	0.774	0.780	0.690
Type of Therapy						

	PF	RF	EF	CF	SF	
Chemotherapy	46.1±20.6	47.5±38.4	41.2±40.0	57.4±30.2	61.8±34.7	72.5±32.8
C and S	52.4±26.8	62.9±33.8	53.8±41.6	58.4±31.4	61.5±33.2	72.4±30.1
CSR	57.4±25.3	66.8±31.8	55.8±43.4	54.6±29.2	67.5±32.4	78.9±24.9
CSH	49.2±14.4	65.3±36.1	61.7±43.1	50.8±35.2	55.0±29.4	80.0±21.9
All [b]	54.9±30.2	67.8±33.6	53.9±47.7	64.7±26.1	63.7±36.0	66.7±29.5
Other [c]	41.1±26.1	47.1±37.7	34.4±44.3	35.6±30.9	44.4±31.9	75.6±25.9
P	0.276	0.168	0.434	0.101	0.273	0.576

PF=Physical Functioning, Role functioning=RF, Emotional functioning=EF, Cognitive functioning = CF, Social functioning=SF,CS= Chemo therapy and surgery, CSR= Chemo therapy, Radio therapy and surgery, CSH= Chemo therapy, surgery and hormonal therapy

*The mean difference is significant at the 0.05 level down the group, according to Tukey HSD Post hoc test

[a] Farming, retired, student

[b] Combination of Chemotherapy, Radiotherapy, Surgery and Hormonal therapy

[c] Surgery only (1),Hormonal therapy only(5),Chemo and Radiotherapy (7),Radio therapy and surgery(1) and surgery and hormonal therapy(1)

5.5. Mean differences between Socio-demographic and clinical variables with EORTC- QLQ-C30 symptom scales

During the analysis of ANOVA for the symptom scales, significant mean difference was observed only for fatigue symptom scale among the educational status groups, in which those breast cancer patients who were below the sixth grade were less fatigued (scored the lowest mean). However, none of the other clinical variables were shown to have significant mean difference with all EORTC-C30 QOL scores (Table 6 summarizes comparison between Socio-demographic and clinical variable and EORTC- QLQ-C30 functional scales).

Table 6: Mean differences between Socio-demographic and clinical variables with EORTC- QLQ-C30 symptom scales

Variable	Fatigue	NV	Pain	Dyspnea	Insomnia	Appetite loss	Constipation	Diarrhea	FI
Age in completed year									
<40	51.2±27.3	58.3±37.9	48.4±32.1	56.2±41.2	52.9±42.3	19.9±31.6	63.7±37.6	64.7±36.9	82.4±29.6
40-49	50.9±27.9	57.2±37.3	48.1±31.5	62.9±40.6	56.0±42.3	20.1±32.3	61.0±33.8	62.3±34.0	82.4±26.6
50-59	48.7±26.9	52.6±39.5	41.3±33.3	54.0±43.8	51.9±42.7	13.2±27.8	66.7±31.7	64.0±34.0	79.9±31.4
>=60	46.9±30.2	50.5±39.4	44.3±29.5	56.3±40.1	54.2±42.1	16.7±28.1	53.1±39.6	56.3±40.1	75.0±33.9
P	0.849	0.672	0.521	0.695	0.960	0.516	0.352	0.700	0.644
Marital Status									
Single	55.6±24.2	53.0±38.0	44.7±20.8	60.6±35.1	59.1±37.0	19.7±35.1	68.2±30.0	66.7±30.9	84.8±24.6
Married	50.3±27.5	57.4±39.9	48.8±32.7	57.3±43.1	53.3±42.5	18.3±30.6	63.3±37.2	64.4±37.2	82.9±29.0
Widowed	46.4±31.7	52.9±33.9	41.4±31.7	54.0±41.2	57.5±43.5	17.2±30.4	52.9±36.2	55.2±37.0	65.5±31.5
Divorced	48.1±26.9	52.1±35.5	38.9±33.6	56.4±39.1	47.9±43.1	15.4±27.4	63.2±31.3	60.7±32.3	81.2±33.2
P	0.664	0.823	0.289	0.955	0.721	0.943	0.430	0.574	0.032

Educational level									
No education	51.9±27.9	57.1±35.5	49.4±31.9	61.0±39.1	56.3±40.6	21.6±31.0	63.6±34.3	61.9±34.5	79.7±32.1
<=6th grade	35.7±25.3*	46.5±43.1	35.7±36.8	45.0±44.2	39.5±43.8	11.6±24.0	55.0±39.8	54.3±41.8	78.3±29.0
7th to 9th	56.6±24.0	53.5±37.0	48.5±30.4	60.6±42.0	51.5±44.9	15.2±30.2	69.7±33.7	72.7±32.8	79.8±33.3
10th to 12th	54.5±26.8	64.5±36.2	51.1±26.9	55.9±42.5	49.5±42.1	20.4±31.8	71.0±37.3	74.2±35.2	86.0±29.5
12th & above	51.5±28.3	56.8±39.5	45.2±30.8	59.1±41.3	62.1±40.0	17.7±32.7	58.6±34.1	59.6±33.8	81.8±26.9
P	0.004	0.357	0.172	0.310	0.084	0.480	0.211	0.069	0.834
Occupation									
Housewife	48.9±27.6	57.4±38.5	46.7±32.0	58.7±41.4	52.8±42.8	16.2±29.1	60.1±37.3	61.7±37.9	81.0±30.3
Gov't employee	54.0±29.4	55.0±39.3	45.0±32.6	57.9±41.6	56.7±42.7	21.6±35.4	65.5±32.7	65.5±32.7	86.0±24.4
Merchant	43.2±26.2	42.9±38.1	39.1±30.2	42.3±42.7	47.4±41.3	20.5±29.9	61.5±36.1	57.7±30.6	71.8±34.9
Other[a]	53.8±23.9	60.7±34.0	51.3±32.2	61.3±39.3	56.0±39.3	16.0±25.7	70.7±32.4	69.3±37.2	77.3±32.9
P	0.324	0.309	0.568	0.285	0.804	0.661	0.500	0.618	0.223
Average monthly income in ETB									
No income	47.1±28.2	50.7±38.6	46.9±34.0	56.4±43.8	51.6±44.6	15.6±29.2	60.9±37.3	59.6±38.1	84.9±27.6
<320	47.4±23.4	61.4±37.9	37.8±26.4	52.0±39.5	46.3±41.4	14.6±26.9	56.1±33.7	60.2±33.5	75.6±33.4
320-700	55.0±29.2	62.9±34.1	56.7±31.3	65.0±39.2	55.8±40.2	20.0±30.0	70.0±38.3	69.2±40.2	76.7±33.1
>701	51.2±28.0	54.1±39.7	44.3±31.9	56.4±41.5	57.1±41.4	20.2±32.9	63.5±33.9	64.2±33.2	81.6±28.8
P	0.448	0.286	0.057	0.552	0.544	0.648	0.348	0.529	0.329
Duration of disease(Time since diagnosis in months)									
<12	50.1±26.9	57.2±37.4	48.5±28.8	58.5±39.5	52.3±40.0	23.1±33.3	65.1±35.6	64.1±35.5	82.6±27.7

13-24	50.7±26.4	55.7±38.1	49.1±32.1	59.7±41.0	58.5±42.3	11.3±26.1	61.0±36.2	61.6±36.0	76.7±32.4
25-36	43.1±28.8	48.0±36.6	43.6±31.8	50.0±39.6	49.0±41.2	10.8±24.2	50.0±33.1	52.9±32.9	77.5±32.5
37-59	52.1±28.1	60.3±42.0	45.3±35.0	65.0±43.2	60.7±43.8	18.8±31.3	68.4±32.4	67.5±33.8	87.2±27.2
>=60	51.6±28.7	55.4±38.5	42.4±33.5	52.0±43.9	48.0±43.9	21.5±32.0	64.4±38.1	65.5±39.1	80.2±30.4
P	0.634	0.736	0.768	0.468	0.510	0.129	0.211	0.448	0.493
Type of Therapy									
Chemotherapy	49.7±23.9	71.6±34.7	43.1±33.4	43.1±43.7	47.1±45.7	15.7±26.7	68.6±34.3	74.5±34.4	84.3±26.7
CS	49.8±27.5	52.5±37.2	46.7±29.8	59.0±40.6	55.0±41.5	19.1±31.2	59.3±36.8	59.5±35.6	76.6±32.7
CSR	47.8±29.1	53.3±39.0	43.6±33.6	56.7±41.8	50.6±43.6	14.4±28.4	63.3±35.1	62.8±37.4	82.2±27.8
CSH	50.0±29.7	55.0±40.1	40.0±37.0	50.0±47.8	50.0±47.8	20.0±32.2	66.7±31.4	63.3±33.1	83.3±32.4
All [b]	51.6±23.2	50.0±46.4	49.0±37.9	56.9±42.1	58.8±38.2	11.8±23.4	62.7±35.1	60.8±35.8	94.1±17.6
Other [c]	58.5±31.3	81.1±28.1	53.3±34.6	62.2±43.4	55.6±43.0	28.9±39.6	77.8±32.5	82.2±33.0	91.1±19.8
P	0.867	0.049	0.875	0.743	0.944	0.585	0.485	0.197	0.146

CS=Chemo therapy and surgery,CSR= Chemo therapy,Radio therapy and surgery,CSH= Chemo therapy, surgery and hormonal therapy

* The mean difference is significant at the 0.05 level down the group, according to Tukey HSD Post hoc test

[a] Farming, retired, student

[b] Combination of Chemotherapy, Radiotherapy, Surgery and Hormonal therapy

[c] Surgery only (1),Hormonal therapy only (5),Chemo and Radiotherapy (7),Radio therapy and surgery(1) and surgery and hormonal therapy(1)

NV= Nausea and vomiting, FI=Financial impact

5.6. Mean differences between Socio-demographic and clinical variable with EORTC-QLQ-BR23 function scales

In the analysis of mean differences between QLQ- BR2 functional scales with socio-demographic and clinical variables; patients' age, marital status and educational level have shown significant mean differences. None of the functional scales have shown significant mean difference among the groups' occupation, average monthly income, time since diagnosis and type of therapy the respondents took.

Participant's above 60 years old were the poorest in sexual functioning (lowest score), those divorced scored poorest in sexual enjoyment. Moreover, widowed respondents had low sexual functioning whereas those who were above 12th grade had the highest score in sexual functioning which implies performing the best in sexual functioning (Table 7 below summarizes comparison between Socio-demographic and clinical variable and EORTC-QLQ-BR23 functional scales).

Table 7: Mean differences between Socio-demographic variables with BR23 function scale

Variable	Body image	Sexual functioning	Sexual enjoyment	Future perspective
Age				
<40	45.3±34.0	29.9±25.5	47.8±28.7	80.1±31.6
40-49	43.7±36.0	32.4±26.4	51.9±26.7	79.9±32.3
50-59	46.7±35.0	31.2±27.8	56.8±18.1	86.8±27.8
>=60	45.1±31.5	16.1±21.8*	50.0±70.7	83.3±28.1
P	0.975	0.026	0.583	0.516
Marital Status				
Single	38.6±30.5	31.1±27.8	61.1±25.1	80.3±35.1
Married	45.1±34.6	33.0±26.1	52.3±25.7	81.7±30.6
Widowed	47.4±35.4	14.9±20.6*	55.6±38.5	82.8±30.4
Divorced	48.1±34.1	21.8±25.1	20.0±18.3*	84.6±27.4
P	0.753	0.001	0.042	0.943
Educational level				
No education	41.2±32.8	22.3±24.4	47.0±26.5	78.4±31.0
<=6th grade	58.5±35.4	26.0±27.5	52.1±17.1	88.4±24.0
7th to 9th	43.9±33.9	34.3±24.6	40.7±29.3	84.8±30.2
10th to 12th	43.0±30.0	32.8±26.7	61.5±23.0	79.6±31.8
12th & above	43.1±35.9	34.3±26.6*	55.6±28.5	82.3±32.7
P	0.090	0.033	0.177	0.480
Occupation				
Housewife	44.8±33.7	26.8±25.4	50.0±27.0	83.8±29.1
Gov't employee	43.7±36.3	35.7±27.9	49.4±26.2	78.4±35.4
Merchant	58.3±33.7	25.0±23.2	55.6±21.7	79.5±29.9
Other[a]	38.0±30.4	30.7±28.3	66.7±33.3	84.0±25.7
P	0.166	0.142	0.521	0.661
Average monthly income in ETB				
No income	46.8±36.3	27.8±27.7	52.5±23.6	84.4±29.2

<320	48.0±30.7	19.9±23.0	58.3±29.5	85.4±26.9
320-700	39.2±30.8	31.3±23.0	35.6±34.4	80.0±30.0
>700	45.5±35.4	33.0±26.9	54.3±23.7	79.8±32.9
P	0.644	0.055	0.084	0.648
Time since diagnosis				
<12	45.4±33.4	24.4±25.7	47.2±32.5	76.9±33.3
13-24	41.4±32.1	23.9±23.5	51.0±29.1	88.7±26.1
25-36	50.5±32.0	32.8±28.0	58.3±22.8	89.2±24.2
37-59	40.2±37.4	35.9±26.4	56.1±19.4	81.2±31.3
>=60	49.0±36.1	31.9±27.0	47.4±25.3	78.5±32.0
P	0.550	0.083	0.581	0.129
Type of therapy				
Chemotherapy	49.0±32.9	24.5±24.4	46.7±29.8	84.3±26.7
CS	44.5±33.2	26.6±26.5	48.1±31.1	80.9±31.2
CSR	46.9±34.3	31.9±26.4	48.4±24.1	85.6±28.4
CSH	53.3±45.5	28.3±24.9	60.0±14.9	80.0±32.2
All [b]	44.1±35.6	44.1±26.3	58.3±15.1	88.2±23.4
Other [c]	36.7±37.4	26.7±22.5	72.2±13.6	71.1±39.6
P	0.861	0.148	0.276	0.585

- PF=Physical Functioning, Role functioning=RF, Emotional functioning=EF, Cognitive functioning = CF, Social functioning=SF,CS= Chemo therapy and surgery, CSR= Chemo therapy, Radio therapy and surgery, CSH= Chemo therapy, surgery and hormonal therapy
- * The mean difference is significant at the 0.05 level down the group, according to Tukey HSD Post hoc test
- [a] Farming, retired, student
- [b] Combination of Chemotherapy, Radiotherapy, Surgery and Hormonal therapy
- [c] Surgery only(1),Hormonal therapy only(5),Chemo and Radiotherapy (7),Radio therapy and surgery(1) and surgery and hormonal therapy(1)

5.7. Mean differences between Socio-demographic and clinical variable with EORTC-QLQ-BR23 symptom scales

Among the BR23 symptom scales, only educational level from the socio demographic characteristics and type of therapy from clinical characteristics of the respondents have shown significant mean difference. However, there was no significant mean difference with the rest of socio demographic characteristics and the duration of disease.

Arm symptoms have shown to occur less among those who were below sixth grade. Breast symptoms were significantly higher among those who were treated with surgery only, hormonal therapy only, chemotherapy and radiotherapy, radio therapy and surgery, and surgery and hormonal therapy (Other c) (Table 8 below summarizes comparison between Socio-demographic and clinical variable and EORTC- QLQ-BR23 symptom scales).

Table 8: Mean differences between Socio-demographic and clinical variables with BR23 symptom scales

Variable	Systemic therapy side effects	Breast Symptoms	Arm Symptoms	Upset by Hair Loss
Age in completed year				
<40	35.2±31.0	61.3±29.5	34.4±27.9	33.3±37.6
40-49	29.1±26.4	59.4±27.5	35.6±28.5	22.2±19.2
50-59	39.4±30.3	59.0±30.1	30.5±28.4	33.3±33.3
>=60	32.6±29.5	52.6±31.0	33.3±30.0	0.0
P	0.306	0.549	0.776	0.612
Marital Status				
Single	39.6±23.7	60.2±28.0	37.4±30.2	
Married	34.8±31.4	60.6±30.7	33.8±27.8	25.5±34.4
Widowed	33.7±30.7	53.4±29.3	34.1±31.3	55.6±19.2
Divorced	31.9±25.4	57.1±24.8	30.2±27.8	16.7±23.6
P	0.805	0.635	0.812	0.314[d]

Educational level				
No education	35.4±28.7	60.0±27.7	36.5±30.5	16.7±19.2
<=6th grade	29.8±29.2	50.6±34.0	20.4±20.3*	41.7±31.9
7th to 9th	34.8±30.4	62.4±27.2	35.4±27.8	33.3±47.1
10th to 12th	41.8±30.8	68.5±28.3	35.1±29.0	27.8±39.0
12th & above	33.5±30.6	58.0±28.9	37.0±28.5	25.0±31.9
P	0.549	0.116	0.022	0.889
Occupation				
Housewife	33.7±29.3	59.2±30.2	32.4±27.8	15.2±17.4
Gov't employee	36.6±31.6	60.2±29.5	38.4±32.0	33.3±42.2
Merchant	32.2±30.1	51.3±29.1	30.3±28.0	55.6±19.2
Other[a]	38.1±28.7	65.3±23.8	32.4±22.4	50.0±70.7
P	0.829	0.386	0.519	0.188
Average monthly income in ETB				
No income	30.3±28.5	55.4±30.1	31.9±26.4	11.1±17.2
<320	29.2±26.7	59.8±25.7	27.9±26.8	16.7±23.6
320-700	44.2±29.9	66.3±30.8	37.8±30.0	44.4±50.9
>701	36.5±31.1	59.0±29.6	35.6±29.7	36.4±34.8
P	0.057	0.316	0.354	0.376
Time since diagnosis				
<12	39.0±30.5	60.9±30.5	35.6±27.9	16.7±18.3
13-24	33.0±29.2	58.5±27.0	31.7±26.5	66.7±33.3
25-36	28.6±24.9	49.8±28.7	28.4±28.8	8.3±16.7
37-59	36.9±30.2	64.1±28.8	36.5±28.5	50.0±23.6
>=60	33.3±31.7	60.2±30.8	34.1±30.3	28.6±40.5
P	0.505	0.298	0.719	0.115
Type of therapy				
Chemotherapy	49.9±32.5	71.6±27.0	30.1±25.7	52.4±32.5
CS	33.8±29.3	56.0±29.9	34.4±29.2	11.1±16.7
CSR	30.6±28.1	58.2±25.7	30.7±27.7	0.0
CSH	31.4±30.5	60.0±30.9	34.4±29.8	16.7±23.6
All [b]	29.7±29.6	55.9±36.2	34.6±23.9	33.3±0

| Other [c] | 48.6±32.0 | 80.6±23.5 | 40.0±31.9 | 50.0±70.7 |
| P | 0.087 | 0.024 | 0.883 | 0.136[d] |

- CS= Chemo therapy and surgery,CSR= Chemo therapy,Radio therapy and surgery,CSH= Chemo therapy, surgery and hormonal therapy
- * The mean difference is significant at the 0.05 level down the group, according to Tukey HSD Post hoc test
- [a] Farming, retired, student
- [b] Combination of Chemotherapy, Radiotherapy, Surgery and Hormonal therapy
- [c] Surgery only(1),Hormonal therapy only(5),Chemo and Radiotherapy (7),Radio therapy and surgery(1) and surgery and hormonal therapy(1)
- [d] Post hoc tests are not performed for Upset by hair loss score because at least one group has fewer than two cases

5.8. Bivariate and Multivariate analysis

Bivariate and multivariate analysis was performed to assess the relative effect of associated factors and functional and symptom scales of EORTC- QLQ-C30 and EORTC- QLQ-BR23 on the outcome variable QoL. The multivariate analysis was performed separately for QoL with socio demographic and clinical variables, EORTC- QLQ-C30 symptom and functional scales and EORTC- QLQ-BR23 symptom and functional scales in a total of 5 different models.

In the bivariate analysis, only average monthly income from socio-demographic variables and type of therapy and duration of disease from clinical characteristics showed significant association. However, in the multivariate analysis clinical variables lost their association and only average monthly income kept its association independently. This means, in comparison with those who have reported that they didn't have income, those who earn 320-700 ETB were about thirty percent less likely to have good (unaffected) quality of life (Table 9). The term affected is used for those participants who said 'Not at all' and unaffected is used for those who said 'A little, quite a little, and very much' for functional scale but the reverse is true for the symptom scale.

In the analysis of the association between EORTC- QLQ-C30 symptom and functional scales, bivariate analysis showed that, except for symptoms of Insomnia, all functional and symptom scales have shown association with QoL. However, after adjusting for confounding variables with multivariate analysis emotional functioning, cognitive functioning, fatigue, nausea and vomiting, appetite loss and financial difficulties maintained their association.

Those who were classified as having unaffected emotional and cognitive functioning were about 2 times more likely to have good QoL. Regarding symptom scales, those who were having less fatigue were less likely to have unaffected QoL. While those who have no problem of nausea and vomiting, appetite loss and financial difficulties were about four, one and half and above two times more likely to have unaffected quality of life respectively (Table 10).

Like wises in the analysis of the association between EORTC-BR23 symptom and functional scales, the bivariate analysis showed significant association between QoL and all functional scales and systemic therapy side effects and breast symptoms have shown significant associations. But in the multivariate analysis all functional scales lost their association while all symptom scales have shown independent association with QoL. Those who have no systemic therapy side effects and have no breast symptom concerns were about four and above two times more likely to have unaffected QoL (Table 11).

(Tables 9-11 summarizes the association between QoL with socio demographic variables, clinical characteristics and EORTC-QLQ-C30 and BR23 functional and symptom scales).

Table 9: Binary and multivariate logistic regression analysis to observe association between Socio-demographic variables and Quality of life

Variable	QOL		COR (95%CI)	AOR (95%CI)
	Affected N(%)	Not affected N(%)		
Age in completed year				
<40	76 (41.3)	26 (39.4)	1	
40-49	41 (22.3)	12 (18.2)	0.9 (0.4, 1.9)	
50-59	43 (23.4)	20 (30.3)	1.4 (0.7, 2.7)	
>=60	24 (13.0)	8 (12.1)	1.0 (0.4, 2.4)	
Marital status				
Single	17 (9.2)	5 (7.6)	1	
Married	117 (63.6)	43 (65.2)	1.3 (0.4, 3.6)	
Widowed	22 (12.0)	7 (10.6)	1.1 (0.3, 4.0)	
Divorced	28 (15.2)	11 (16.7)	1.3 (0.4, 4.5)	
Educational level				
No education	58 (31.5)	19 (28.8)	1	
<=6th grade	30 (16.3)	13 (19.7)	1.3 (0.6, 3.0)	
7th to 9th	22 (12.0)	11 (16.7)	1.5 (0.6, 3.7)	
10th to 12th	25 (13.6)	6 (9.1)	0.7 (0.3, 2.1)	
12th & above	49 (26.6)	17 (25.8)	1.1 (0.5, 2.3)	
Occupation				
Housewife	102 (55.4)	40 (60.6)	1	
Gov't employee	45 (24.5)	12 (18.2)	0.7 (0.3, 1.4)	
Merchant	17 (9.2)	9 (13.6)	1.4 (0.6, 3.3)	
Other[a]	20 (10.9)	5 (7.6)	0.6 (0.2, 1.8)	
Average monthly income in ETB				
No income	49 (26.6)	26 (39.4)	1	1
<320	29 (15.8)	12 (18.2)	0.8 (0.3, 1.8)	0.8 (0.3, 2.0)
320-700	33 (17.9)	7 (10.6)	0.4 (0.2, 1.0)	0.3 (0.1, 0.9)*
>700	73 (39.7)	21 (31.8)	0.5 (0.3, 1.1)	0.6 (0.3, 1.2)
Duration of disease(Time since diagnosis in months)				
<12	51 (27.7)	14 (21.2)	1	1
13-24	36 (19.6)	17 (25.8)	1.7 (0.8, 3.9)	1.7 (0.7, 4.1)

25-36	24 (13.0)	10 (15.2)	1.5 (0.6, 3.9)	1.3 (0.5, 3.8)
37-59	30 (16.3)	9 (13.6)	1.1 (0.4, 2.8)	0.9 (0.3, 2.6)
>=60	43 (23.4)	16 (24.2)	1.4 (0.6, 3.1)	1.3 (0.5, 3.1)
Type of Therapy				
Chemotherapy	16 (8.7)	1 (1.5)	1	1
C and S	94 (51.1)	37 (56.1)	6.3 (0.8, 49.2)	6.1 (0.8, 48.7)
CSR	41 (22.3)	19 (28.8)	7.4 (0.9, 60.1)	6.8 (0.8, 57.4)
CSH	9 (4.9)	1 (1.5)	1.8 (0.1, 32.0)	1.5 (0.1, 28.1)
All [b]	11 (6.0)	6 (9.1)	8.7 (0.9, 83.0)	7.5 (0.7, 78.2)
Other [c]	13 (7.1)	2 (3.0)	2.5 (0.2, 30.3)	2.7 (0.2, 33.6)

> *Statistically significant at P<0.05

> [a] Farming, retired, student

> [b] Combination of Chemotherapy, Radiotherapy, Surgery and Hormonal therapy

> [c] Surgery only(1),Hormonal therapy only(5),Chemo and Radiotherapy (7),Radio therapy and surgery (1) and surgery and hormonal therapy(1).

Table 10: Binary and multivariate logistic regression analysis to observe association between EORTC- QLQ-C30 functioning and symptom scales with quality of life

Variable		QOL		COR (95%CI)	AOR (95%CI)
		Affected N(%)	**Not affected N(%)**		
Functional scales					
Physical functioning	Affected N(%)	125 (67.9)	23 (34.8)	1	1
	Not affected N(%)	59 (32.1)	43 (65.2)	4.0 (2.2, 7.2)*	1.5 (0.6, 3.4)
Role functioning	Affected N(%)	126 (68.5)	22 (33.3)	1	1
	Not affected N(%)	58 (31.5)	44 (66.7)	4.3 (2.4, 7.9)*	1.7 (0.7, 3.9)
Emotional functioning	Affected N(%)	137 (74.5)	24 (36.4)	1	1
	Not affected N(%)	47 (25.5)	42 (63.6)	5.1 (2.8, 9.3)*	2.1 (1.0, 4.4)*
Cognitive	Affected N(%)	128 (69.6)	23 (34.8)	1	1

functioning	Not affected N(%)	56 (30.4)	43 (65.2)	4.3 (2.4, 7.8)*	2.2 (1.1, 4.4)*
Social	Affected N(%)	102 (55.4)	20 (30.3)	1	1
functioning	Not affected N(%)	82 (44.6)	46 (69.7)	2.9 (1.6, 5.2)*	1.7 (0.9, 3.2)
Symptom scale					
Fatigue	Affected N(%)	143 (77.7)	46 (69.7)	1	1
	Not affected N(%)	41 (22.3)	20 (30.3)	1.5 (0.8, 2.8)	0.3 (0.1, 0.8)*
Nausea and vomiting	Affected N(%)	150 (81.5)	33 (50.0)	1	1
	Not affected N(%)	34 (18.5)	33 (50.0)	4.4 (2.4, 8.1)*	4.0 (2.0, 7.9)*
Pain	Affected N(%)	142 (77.2)	41 (62.1)	1	1
	Not affected N(%)	42 (22.8)	25 (37.9)	2.1 (1.1, 3.8)*	1.6 (0.7, 4.1)
Dyspnea	Affected N(%)	140 (76.1)	42 (63.6)	1	1
	Not affected N(%)	44 (23.9)	24 (36.4)	1.8 (1.0, 3.3)*	1.4 (0.5, 3.4)
Insomnia	Affected N(%)	127 (69.0)	44 (66.7)	1	
	Not affected N(%)	57 (31.0)	22 (33.3)	1.1 (0.6, 2.0)	
Appetite loss	Affected N(%)	62 (33.7)	13 (19.7)	1	1
	Not affected N(%)	122 (66.3)	53 (80.3)	2.1 (1.1, 4.1)*	2.3 (1.0, 5.0)*
Constipation	Affected N(%)	161 (87.5)	45 (68.2)	1	1
	Not affected N(%)	23 (12.5)	21 (31.8)	3.3 (1.7, 6.4)*	1.5 (0.4, 5.6)
Diarrhea	Affected N(%)	162 (88.0)	45 (68.2)	1	1
	Not affected N(%)	22 (12.0)	21 (31.8)	3.4 (1.7, 6.8)*	2.3 (0.6, 8.9)
Financial difficulties	Affected N(%)	178 (96.7)	55 (83.3)	1	1
	Not affected N(%)	6 (3.3)	11 (16.7)	5.9 (2.1, 16.8)*	4.7 (1.5, 15.1)*

➢ *Statistically significant at P<0.05

➢ [a] Farming, retired, student

➢ [b] Combination of Chemotherapy, Radiotherapy, Surgery and Hormonal therapy

➢ [c] Surgery only(1),Hormonal therapy only(5),Chemo and Radiotherapy (7),Radio therapy and surgery (1) and surgery and hormonal therapy(1).

Table 11: Binary and multivariate logistic regression analysis to observe association between EORTC-BR23 functioning and symptom scales with quality of life

Variable		QOL		COR (95%CI)	AOR (95%CI)
		Affected N(%)	Not affected N(%)		
Functional scales					
Body image	Affected N(%)	130 (70.7)	36 (54.5)	1	1
	Not affected N(%)	54 (29.3)	30 (45.5)	2.0 (1.1, 3.6)	2.0 (0.8, 5.2)
Sexual functioning	Affected N(%)	174 (94.6)	65 (98.5)	1	1
	Not affected N(%)	10 (5.4)	1 (1.5)	0.3 (0.0, 2.1)	0.4 (0.0, 3.1)
Sexual enjoyment	Affected N(%)	73 (94.8)	22 (88.0)	1	1
	Not affected N(%)	4 (5.2)	3 (12.0)	2.5 (0.5, 12.0)	2.9 (0.6, 15.3)
Future perspective	Affected N(%)	62 (33.7)	13 (19.7)	1	1
	Not affected N(%)	122 (66.3)	53 (80.3)	2.1 (1.1, 4.1)	2.2 (0.6, 7.6)
Symptom scale					
Systemic therapy SE	Affected N(%)	120 (65.2)	19 (28.8)	1	1
	Not affected N(%)	64 (34.8)	47 (71.2)	4.6 (2.5, 8.6)	4.0 (2.1, 7.5)*
Breast Symptoms	Affected N(%)	170 (92.4)	50 (75.8)	1	1
	Not affected N(%)	14 (7.6)	16 (24.2)	3.9 (1.8, 8.5)	2.5 (1.1, 5.7)*
Arm Symptoms	Affected N(%)	103 (56.0)	36 (54.5)	1	
	Not affected N(%)	81 (44.0)	30 (45.5)	1.1 (0.6, 1.9)	
Upset by Hair Loss	Affected N(%)	10 (58.8)	2 (40.0)	1	
	Not affected N(%)	7 (41.2)	3 (60.0)	2.1 (0.3, 16.4)	

> *Statistically significant at P<0.05

> [a] Farming, retired, student

> [b] Combination of Chemotherapy, Radiotherapy, Surgery and Hormonal therapy

[c] Surgery only(1),Hormonal therapy only(5),Chemo and Radiotherapy (7),Radio therapy and surgery(1) and surgery and hormonal therapy (1) (Heydarnejad, Hassanpour, and Solati 2011)

6. DISCUSSION

The scores of QoL provide many useful data on the influence of a disease on various spheres of life of affected individuals. This study assessed QoL among female breast cancer patients at TASRH. The main findings of this study showed that patients with breast cancer had low QoL. Moreover, the role functioning and social functioning of the participants were low. The participants scored high symptom scales except for pain and appetite loss which implies that they were symptomatic. On the other hand, a high score of future perspective was observed compared to some other studies which might be due to social support from the community and family members. On the QLQ-BR23 symptom scales, only educational level from the socio-demographic characteristics and type of therapy from clinical characteristics of the respondents showed a significant mean difference.

The mean score for QoL was 52.5 (SD: 26.0) which is lower than the EORTC reference value (61.8 ±24.6) (Scott et al. 2008). The QOL mean score was also found to be lower than studies done elsewhere; such as in India, Melbourne, Nepal, Bahrain and Brazil (Safaee et al. 2008, Dubashi et al. 2010, Grabsch et al. 2006, Manandhar et al. 2014, Jassim and Whitford 2013, Lôbo et al. 2014). This reveals poorer QoL among Ethiopian breast cancer patients in comparison with other patients elsewhere. The reported lower QoL among Ethiopian breast cancer patients might be due to the fact that most of the patients travel long distances to the hospital from different corners of the country to get appropriate cancer-related treatment. This might put clients in different social, economical and psychological crisis which in turn might lead to the reduced QoL. Most breast cancer patients should wait for longer periods of time to get the first treatment due to the low capacity of the hospital to treat a large number of patients at a time. Moreover, a study by Tigeneh et al. (2015) reiterated that most of the breast cancer patients in the hospital are at an advanced stage of cancer which might be a reason for poor prognosis and reduced QoL.

Furthermore, the difference in the global health status observed can be partially due to the different study design employed for this particular study compared to studies given above. Whereby unlike some other studies referred here, this study did not compare QoL of the same individuals at several time intervals but rather compared different subjects with various

clinical backgrounds such as time elapsed since diagnosis, type of therapy they obtained and the stage of cancer. In addition, the differences can be attributed to the fact that enrolled patients in this study were undergoing different forms of treatment compared to some studies that focused on patients attending follow-up clinic only or appointment for chemotherapy only or after breast surgery and so forth. Reduced global QoL amongst Ethiopian women compared with other patients studied elsewhere might be related to the absence of social, economic and psychological support for breast cancer patients from the health care system, however, this aspect was beyond the scope of this study.

In this study, the EORTC functional scale scores ranged from a mean of 52.6 (SD 42.6) for role functioning, to a mean of 74.1 (SD 28.59) for social functioning even though the items discriminatory ability was shown to be poor (α =0.32). Both the role functioning and social functioning were lower in comparison with the reference data (Ranging a mean of 70.9 for role functioning to 77.0 for social functioning) (Scott et al. 2008). The findings of this study were lower compared to studies conducted in India (Dubashi et al. 2010), Australia (Grabsch et al. 2006), Nepal (Manandhar et al. 2014), Bahrain (Jassim and Whitford 2013) and Brazil (Lôbo et al. 2014). On the other hand, the social and emotional functional scales were higher than a study done in Nepal (Manandhar et al. 2014). Reduced physical, social and role functioning might be due to the fact that most of the breast cancer patients in the hospital have advanced breast cancer which can hinder their functioning from different social activities. Moreover, the role of the participants in the family might be a factor. Most of the women in developing countries like Ethiopia are expected to take care of the whole family including making money for living, taking care of the children, house works etc. Therefore, the presence of advanced stage breast cancer can hold them back from doing the difficult roles of housewives in the family.

Regarding the EORTC QLQ-C30 symptom scales, except for pain and appetite loss all symptoms scales received scores above the mean of 50; implying that most of the breast cancer patients had symptoms such as trouble doing strenuous activities, limited in doing daily activities or pursuing their hobbies, had trouble sleeping and had difficulty in concentrating on things. Higher scores of symptom scale in this research was also observed in comparison with another study done in India; where less severe symptoms of diarrhea,

constipation, dyspnea, nausea and vomiting and appetite loss were reported (Safaee et al. 2008). A Report in Brazil also depicted a comparatively lower scores in insomnia (37.93), fatigue (36.01) and loss of appetite (33.56) (Lôbo et al. 2014). These poor functioning and higher levels of symptomatology in Ethiopian patients might be caused by poor economical status. Most of the participants of the study (62.4%) had an average monthly income of lower than 35 USD which could make it difficult to cover the expensive costs of treatment. This, in turn, will reduce the amount of patients who will visit health care centers before worsening of the symptoms. The multifaceted burden of breast cancer in the Ethiopian women context is even more pronounced by the fact that there is only one radiotherapy center in the country. This might have implication in terms of the amount of time a patient should wait before getting the proper cancer-related medical treatment which in turn may contribute to worsening of symptoms. The findings of this research may provide support for planning health care institutions which can provide adequate treatment for patients with breast cancer.

When it comes to the scales/items of QLQ-BR23's functioning scale, a high score of future perspective was observed as compared to some other studies such as a study done in Brazil (Lôbo et al. 2014). This implies that patients had less worries about their future health. Future perspective was found to be better in this study compared with other studies might be due to the fact that Ethiopian women might receive psychological and social support through informal ways such as family, religious institution or the wider society; as social support is reported to enhance better QoL among patients with breast cancer (Leung, Pachana, and McLaughlin 2014). The high score of future perspective, on the other hand, might signal that most of the participants did not know about the prognosis of breast cancer and the treatment outcome. Most of the participants of the study (73.6%) had an educational background less that grade 12. This might hinder their awareness about the prognosis of the disease and treatment outcomes, and they might think that they will be cured of cancer after the completion of the treatment; which is difficult even with the presence of most advanced treatment options in developed countries. In the same category, sexual satisfaction and enjoyment scored a lower mean; which reveals that the practice of sexual intercourse and satisfaction was affected for most patients compared to a study conducted in Brazil (Lôbo et al. 2014). In the QLQ-BR23's symptom scale, all symptom items except for breast symptoms, in which there were problems like swelling, pain and tenderness on the breast; scored mean scores of below 50.

Furthermore, findings of this study on other aspects of QLQ-BR23 functional scale were lower than a study conducted in India; which reported higher functional scores of sexual function and sexual enjoyment (Dubashi et al. 2010). The findings of this study revealed lower functional scale compared to a study in Brazil which revealed high score on body image (Lôbo et al. 2014). Comparable findings were reported in a study in Nepal in which lower functioning and higher symptom scores in which women scored poorly in most of the scales (Manandhar et al. 2014). Besides, poorer scores compared to this study were reported in a study among Bahraini women whereby on the symptom scale, upset due to hair loss scored a mean of 46.3 (Jassim and Whitford 2013). A study in Brazil showed 50.07 as a mean score for side effects, meaning that many women experience side effects of chemotherapy which is higher than our study (mean 34.6) (Lôbo et al. 2014).

In this study, during the assessment of mean differences between socio-demographic variables and EORTC- QLQ-C30 functioning scales, there was no significant mean difference across the age group, marital status, educational status, duration of disease and type of therapy with all functional scales of EORTC questionnaire. However, there was a significant mean difference of monthly income in which those who were earning 320-700 ETB scored the lowest mean (poorest functioning) on physical and emotional functioning than those earning lower or higher than them. Unlike in this study, among Bahraini breast cancer patients, there were significant differences in the global health means across categories of educational level, marital status and type of surgery (Jassim and Whitford 2013). In a study done in Nepal, QoL was found to be good in patients who were literate, older, housewives, women who had been diagnosed for less than 6 months and patients who underwent breast conserving surgery or lumpectomy (Manandhar et al. 2014). A study in China also demonstrated the association between QoL measures and age, level of education and occupation (Yan et al. 2016). Moreover, a study done in India, among demographic factors, occupational status and duration of disease were significantly related to QoL score of patients (Safaee et al. 2008). However, similar to this study there were significant differences in the global health means across categories of monthly income among Bahraini (Jassim and Whitford 2013), Nepali (Manandhar et al. 2014) and Chinese (Yan et al. 2016) breast cancer patients. Comparable results reported in India; in which no significant association was observed between EORTC- QLQ-C30 functioning scales and duration of disease and type of therapy (Safaee et al. 2008). These inconsistent mean differences between socio-demographic

and clinical variables might be related with the health care systems in which some countries might give priority for certain socio-demographic characters. For instance, there might be free medical services to elderly people or to those with poor economic status. Contrary to this, in some countries like Ethiopia, those disadvantaged groups might be forced to shoulder the disease symptoms in addition to medical costs. Moreover, some countries have psychological and social support in their health care delivery system and others might not have. Therefore, a country like Ethiopia needs to reinforce the health system by providing more resources to help the needy.

During the assessment of mean differences between socio-demographic variables and EORTC- QLQ-C30 symptom scales, the only significant mean difference was observed for the educational status group. Here, fatigue had lower mean score among breast cancer patients who were below the sixth grade. However, none of the clinical variables were shown to have a significant mean difference with any of the assessed symptom scales. A study in Poland, however, showed significant intergroup differences with regards to the severity of such symptoms as fatigue, nausea and vomiting, pain, insomnia, appetite loss, constipation and diarrhea (Kulesza-Bronczyk et al. 2014). Pain was associated with age in Bahraini breast cancer patients (Jassim and Whitford 2013) and in the UK younger women reported more physical symptoms, social and financial difficulties whereas CT rather than age was associated with increased fatigue (Hopwood et al. 2008). This might indicate that, Ethiopian breast cancer patients might be equally affected in which whether the patient is educated or not, or wealthy or poor; even though there might have different access for therapy, whoever the patients are they were forced to wait for their turn for the only radiotherapy center which is currently serving for patients coming from all over the country.

In the analysis of mean differences between QLQ- BR23 functional scales with socio-demographic and clinical variables; patients age, marital status, educational level have shown significant differences. However, occupation, average monthly income, duration of disease and type of therapy did not show significant mean difference among the groups. Participant's above 60 years were the poorest in sexual functioning (lowest score) as compared to those younger (< 60) participants. However, participants who were above 12th grade had the highest score in sexual functioning meaning performing the best in sexual functioning. Similar with

the findings of this study, in Bahraini breast cancer patients, better sexual functioning was observed for married women (Jassim and Whitford 2013). In a longitudinal study done in a Finish hospital, there were no significant changes in sexual functioning with time since diagnosis (Salonen et al. 2011a). Another study in Nepal showed that those older, literate, housewives, who had been diagnosed for less than 6 months and who had been receiving chemotherapy treatment only were found to have statistically significant association with body image function (Manandhar et al. 2014). The reduced sexual functioning in elderly patients might be due to menopause which can reduce sexual activity. When it comes to marital status, those divorced scored poorest sexual enjoyment which might be due to lack of support from the spouse. Contrary, those married might get support from their spouses. When it comes to the educational status, those who were 12th grade and above might freely discuss about sexuality and might understand the changes related with the disease and respond accordingly which in turn might contribute to good sexual functioning.

In contrast to the findings of this study, in Poland, both sexual functioning and sexual enjoyment scores of patients turned out to be significantly lower in cases where time since diagnosis was longer (Kulesza-Bronczyk et al. 2014). In Bahraini breast cancer patients body image was significantly associated among categories of educational level and mastectomy; where participants who had undergone mastectomy and were highly educated tended to have poorer body image (Jassim and Whitford 2013). A study in India showed slightly less body image scores in those with more than six years of follow-up (Dubashi et al. 2010). Unlike the results of this study, a study in Finland showed that women receiving no chemotherapy and no hormonal therapy had a smaller risk of decreased body image scores, while employed women had a greater risk of negative changes in body image than retired women (Salonen et al. 2011a). The difference in the result of this study with other studies might be due to the difference in socio-demographic characteristics.

Among the BR23 symptom scales, only educational level from the socio-demographic characteristics and type of therapy from clinical characteristics of the respondents had shown a significant mean difference. However, there was no significant mean difference with the rest of socio-demographic characteristics and duration of disease. According to the findings of this study, arm symptoms have shown to occur less among those who were below the sixth

grade which might be due to the fact that those educated patients might understand the disease prognosis and might feel free to express the symptoms. Whereas, breast symptoms were significantly higher among those who were treated with surgery only, hormonal therapy only, chemotherapy and radiotherapy, radiotherapy and surgery and surgery and hormonal therapy. This might be related with the fact that combination of therapy is better than single therapy for a better outcome including reduced pain and other symptoms. Moreover, the experience of breast symptoms might be due to the toxic nature of cancer therapy which is related with different side effects. For instance, anti-cancer medications are known to cause vomiting and breast surgery might be related with body image disturbance. In contrast to these findings, Bahraini breast cancer patients who were recently diagnosed were more worried about their future, complained of more breast symptoms and were more upset by the loss of their hair (Jassim and Whitford 2013). In Iran, except for future perspective; there were significant deteriorations in all other patients' functioning scores over time compared to the baseline assessment (Montazeri et al. 2008). As shown by a longitudinal study done in Finish hospital, six months after surgery participants had; decreased body image, negative changes in systematic side-effects, decreased arm symptoms and breast symptoms and improved future outlook significantly (Salonen et al. 2011a)

Furthermore, as shown by the multivariate analysis, participants who were classified as having unaffected emotional and cognitive functioning were about 2 times more likely to have good QOL. Regarding symptom scales, those who were having less fatigue were less likely to have unaffected QoL. On the other hand, those who have no problem with nausea and vomiting, appetite loss and financial difficulties were more likely to have unaffected QoL.

STUDY LIMITATION

This is quantitative study done using a structured questionnaire; hence it may be difficult to elaborate the explanation for the responses of study participants. Furthermore, since the nature of this study was a cross sectional one, it hinders the possibilities of assessing for cause and effect relationships. Moreover, a cross sectional study design may limit the progressive investigation of quality of life improvements following a series of intervention strategies.

7. CONCLUSION AND RECOMMENDATIONS

7.1. Conclusion

Ethiopian breast cancer patients reported poor quality of life as it is compared to many international findings and attention should be given to improve their QoL. Participants had low role functioning and social functioning. Moreover, most participants of the study were symptomatic. On the other hand, a high score of future perspective was observed. During the analysis of the mean differences between socio-demographic variables and participants QoL functioning scale, most of the socio-demographic variables, except the level of income of participants, did not show significant association with QoL. Furthermore, analysis of the mean differences between socio-demographic variables and participants QoL symptom scale showed that the only significant mean difference was observed for the educational status. Moreover, no significant association was identified between type and duration of treatment and QoL of participants.

7.2 Recommendations

➢ It is important that QoL assessments should be included in patient treatment protocols in which addressing those functional and symptom scales helps to improve the quality of life of breast cancer patients.

➢ Healthcare providers need to focus on addressing side effects of therapy, psychosocial and economic support to minimize systemic therapy side effects and symptoms which intern will help improve quality of life of women with breast cancer.

➢ Since there is a single radio therapy centre in Ethiopia, breast cancer patients have to shoulder double burden of disease related problems and waiting for service which can be a reason for reduced QoL of patients. Hence, the government should consider expansion of oncology centre.

➢ Lastly it is recommended that further research including qualitative data and control groups of women without breast cancer might help to explore the effect of breast cancer on quality of life.

BIBLIOGRAPHY

Aaronson, NK., S. Ahmedzai, B. Bergman, M. Bullinger, A. Cull, NJ. Duez, A. Filiberti, H. Flechtner, SB. Fleishman, JCJM. de H, S. Kaasa, MC. Klee, D. Osoba, D. Razavi, PB. Rofe, S. Schraub, KCA Sneeuw, M Sullivan, and F. Takeda. 1993. "The European Organisation for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology." *Journal of the National Cancer Institute* 85:365-376.

Alzabaidey, FJ. 2012. "Quality of Life Assessment for Patients with Breast Cancer Receiving Adjuvant Therapy." *Quality of Life Assessment for Patients with Breast Cancer Receiving Adjuvant Therapy* 4. doi: 10.4172/1948-5956.1000110.

Benson, John, and Ismail Jatoi. 2012. The global breast cancer burden. London: Future Medicine Ltd.

Boehmer, Ulrike, Mark Glickman, Jacqui Milton, and Michael Winter. 2012. "Health-related quality of life in breast cancer survivors of different sexual orientations." *An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation - Official Journal of the International Society of Quality of Life Research* 21 (2):225-236. doi: 10.1007/s11136-011-9947-y.

Bowling, A. 1995. "What things are important in people's lives? A survey of the public's judgements to inform scales of health related quality of life." *Soc Sci Med* 41 (10):1447-62.

Dubashi, B., E. Vidhubala, S. Cyriac, and T. Sagar. 2010. "Quality of life among young women with breast cancer: Study from a tertiary cancer institute in south India." *Indian Journal of Cancer* 47 (2):142-147. doi: 10.4103/0019-509X.63005.

Grabsch, Brenda, David M. Clarke, Anthony Love, Dean P. McKenzie, Raymond D. Snyder, Sidney Bloch, Graeme Smith, and David W. Kissane. 2006. "Psychological morbidity and quality of life in women with advanced breast cancer: A cross-sectional survey." *Pall Supp Care* 4 (1):47-56. doi: 10.1017/S1478951506060068.

Heydarnejad, M. S., Dehkordi A. Hassanpour, and Dehkordi K. Solati. 2011. "Factors affecting quality of life in cancer patients undergoing chemotherapy." *African health sciences* 11 (2):266.

Hopwood, Penelope, Joanne Haviland, Judith Mills, Georges Sumo, and Judith M. Bliss. 2008. Corrigendum to "The impact of age and clinical factors on quality of life in early breast cancer: An analysis of 2208 women recruited to the UK START Trial (Standardisation of Breast Radiotherapy Trial)".

Jassim, Ghufran Ahmed, and David L. Whitford. 2013. "Quality of life of Bahraini women with breast cancer: a cross sectional study." *BMC Cancer* 13:212-212. doi: 10.1186/1471-2407-13-212.

Kinamore, Cher. 2008. "Assessing and supporting body image and sexual concerns for young women with breast cancer: a literature review." *J Radiother Pract* 7 (3):159-171. doi: 10.1017/S1460396908006377.

Knaul, Felicia Marie, Frenk, Julio and Shulman, Lawrence. 2011. *Global Task Force on Expanded Access to Cancer Care and Control in Developing Countries. Closing the Cancer Divide: A Blueprint to Expand Access in Low and Middle Income Countries*: Harvard Global Equity Initiative.

Kulesza-Bronczyk, B., B. Dobrzycka, K. Piekut, R. Terlikowski, B. Mackowiak-Matejczyk, A. Wojno, and S. J. Terlikowski. 2014. "Quality of life during the first year after breast cancer resection." *Progress in Health Sciences* 4 (1):124.

Larsson, Jenny, Kerstin Sandelin, and Christina Forsberg. 2010. "Health-Related Quality of Life and Healthcare Experiences in Breast Cancer Patients in a Study of Swedish Women." *Cancer Nursing* 33 (2):164-170. doi: 10.1097/NCC.0b013e3181bb0d05.

Lesley, Fallowfield. 2002. "Quality of life: a new perspective for cancer patients." *Nature Reviews Cancer* 2 (11):873. doi: 10.1038/nrc930.

Leung, Janni, Nancy A. Pachana, and Deirdre McLaughlin. 2014. "Social support and health-related quality of life in women with breast cancer: a longitudinal study." *Psycho-Oncology* 23 (9):1014-1020. doi: 10.1002/pon.3523.

Lôbo, Sâmya, Ana Fernandes, Paulo de Almeida, Carolina Carvalho, and Namie Sawada. 2014. "Quality of life in women with breast cancer undergoing chemotherapy/Qualidade de vida em mulheres com neoplasias de mama em quimioterapia." *Acta Paulista de Enfermagem* 27 (6):554-559.

Manandhar, S., D. S. Shrestha, P. Taechaboonsermsk, S. Siri, and J. Suparp. 2014. "Quality of life among breast cancer patients undergoing treatment in national cancer centers in Nepal." *Asian Pac J Cancer Prev* 15 (22):9753-7.

Michelle, Grayson. 2012. "Breast cancer." *Nature* 485 (7400):S49. doi: 10.1038/485S49a.

Montazeri, Ali. 2008. "Health-related quality of life in breast cancer patients: A bibliographic review of the literature from 1974 to 2007." *Journal of Experimental & Clinical Cancer Research : CR* 27 (1):32-32. doi: 10.1186/1756-9966-27-32.

Montazeri, Ali, Mariam Vahdaninia, Iraj Harirchi, Mandana Ebrahimi, Fatemeh Khaleghi, and Soghra Jarvandi. 2008. "Quality of life in patients with breast cancer before and after diagnosis: an eighteen months follow-up study." *BMC Cancer* 8 (1):330. doi: 10.1186/1471-2407-8-330.

Moro-Valdezate, David, Elvira Buch-Villa, Salvador Peiró, M. Morales-Monsalve, Antonio Caballero-Gárate, Ángel Martínez-Agulló, Félix Checa-Ayet, and Joaquín Ortega-Serrano. 2014. "Factors associated with health-related quality of life in a cohort of Spanish breast cancer patients." *Breast Cancer* 21 (4):442-452. doi: 10.1007/s12282-012-0402-x.

Obrist, Mark, Ernest Osei-Bonsu, Baffour Awuah, Shinobu Watanabe-Galloway, Sofia D. Merajver, Kendra Schmid, and Amr S. Soliman. 2014. "Factors related to incomplete treatment of breast cancer in Kumasi, Ghana." *The Breast* 23 (6):821-828. doi: 10.1016/j.breast.2014.08.014.

Ogundiran, Temidayo O., Sally Nneoma Sarah Akarolo-Anthony, and Clement Adebayo Adebamowo. 2010. "Emerging Breast Cancer Epidemic: Evidence from Africa." *Breast Cancer Research*. doi: 10.1186/bcr2737.

Omotara, B., S. Yahya, M. Amodu, and J. Bimba. 2012. "Awareness, Attitude and Practice of Rural Women regarding Breast Cancer in Northeast Nigeria." *J Community Med Health Educ* 1. doi: 10.4172/2161-0711.1000148.

Parkin, D. M., F. Bray, J. Ferlay, and A. Jemal. 2014. "Cancer in Africa 2012." *Cancer Epidemiol Biomarkers Prev* 23 (6):953-66. doi: 10.1158/1055-9965.epi-14-0281.

Perry, Sheila, Theresa L. Kowalski, and Chih-Hung Chang. 2007. "Quality of life assessment in women with breast cancer: benefits, acceptability and utilization." *Health and Quality of Life Outcomes* 5 (24):24.

Poradzisz, Michele, and Kristine L. Florczak. 2013. "Quality of Life." *Nursing Science Quarterly* 26 (2):116-120. doi: 10.1177/0894318413477149.

Safaee, A., B. Moghimi-Dehkordi, B. Zeighami, H. Tabatabaee, and M. Pourhoseingholi. 2008. "Predictors of quality of life in breast cancer patients under chemotherapy." *Indian Journal of Cancer* 45 (3):107-111. doi: 10.4103/0019-509X.44066.

Salonen, Paivi, Pirkko-Liisa Kellokumpu-Lehtinen, Marja-Terttu Tarkka, Anna-Maija Koivisto, and Marja Kaunonen. 2011a. "Changes in quality of life in patients with breast cancer.(Clinical report)." *Journal of Clinical Nursing* 20 (1 2):255.

Salonen, Päivi, Pirkko-Liisa Kellokumpu-Lehtinen, Marja-Terttu Tarkka, Anna-Maija Koivisto, and Marja Kaunonen. 2011e. "Changes in quality of life in patients with breast cancer." *Journal of Clinical Nursing* 20 (1-2):255-266. doi: 10.1111/j.1365-2702.2010.03422.x.

Scott, Neil W., Peter M. Fayers., Neil K. Aaronson., Andrew Bottomley., Alexander de Graeff., Mogens Grønvold., Chad Gundy., Michael Koller., Morten Aagaard Petersen., and Mirjam A. G. Sprangers. 2008. " "EORTC QLQ-C30 Reference Values." ".

Shulman, Lawrence Nathan, Walter C. Willett, Amy Claire Sievers, and Felicia Marie Knaul. 2010. "Breast Cancer in Developing Countries: Opportunities for Improved Survival." *Journal of Oncology*. doi: 10.1155/2010/595167.

Tadele, Niguse. 2015. "Evaluation of quality of life of adult cancer patients attending Tikur Anbessa specialized referral hospital, Addis Ababa Ethiopia." *Ethiopian journal of health sciences* 25 (1):53.

Tigeneh, T., A. Molla, A. Abreha, and M. Assefa. 2015. "Pattern of Cancer in Tikur Anbessa Specialized Hospital Oncology Center in Ethiopia from 1998 to 2010." *Int J Cancer Res Mol Mech* 1. doi: http://dx.doi.org/10.16966/2381-3318.103.

WHO. 2015. Cancer - a Growing Public Health Concern for Ethiopia.

WHO. 2016. WHOQOL: Measuring Quality of Life.

WHOQOLGROUP. 1998. "Development of the World Health Organization WHOQOL-BREF quality of life assessment. The WHOQOL Group." *Psychol Med* 28 (3):551-8.

Woldeamanuel, Y. W., B. Girma, and A. M. Teklu. 2013. "Cancer in Ethiopia." *Lancet Oncol* 14 (4):289-90. doi: 10.1016/s1470-2045(12)70399-6.

Yan, Bei, Li-Ming Yang, Li-Peng Hao, Chen Yang, Lei Quan, Li-Hong Wang, Zheng Wu, Xiao-Pan Li, Yu-Tang Gao, Qiao Sun, and Jian-Min Yuan. 2016. "Determinants of Quality of Life for Breast Cancer Patients in Shanghai, China.(Report)." *PLoS ONE* 11 (4). doi: 10.1371/journal.pone.0153714.

ANNEX I- Informaion sheet for the doctor/nurse in the Oncology unit

Request to invite women with breast cancer who are patients at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia 2015 to participate in the project "Assessing quality of life among Ethiopian women with breast cancer"

The purpose of this study is to assess the quality of life of patients with breast cancer at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia. The research is a master thesis in International Social Welfare and Health Policy at Oslo and Akershus University College of applied science, Oslo, Norway. The researcher and interviewer is an Ethiopian woman, who can speak Amharic, while her supervisor is Amy Østertun Geirdal, a Norwegian professor. The study is approved both from the Tikur Anbassa specialized hospital as well as the Regionale Komiteer for Medisinskog Helsefaglig Forskningsetikk (REK) in Norway, which are founded on the Norwegian law on research ethics and medical research.

The data will be collected at the Oncology Unit and it will be collected through direct face to face interview of the participants with the data collector. You are kindly asked to ask the female breast cancer patients if they are willing to participate in the study, and direct those patients who are willing to the researcher who will be waiting in another room at the Unit after the consultation with you. Kindly inform that the data collection may take approximately 40 minutes.

If convenient with you, it is appreciated if an informed consent, written or oral will be obtained from the clients before they meet the researcher. Those of the patients who can read and write will sign the consent themselves after reading the invitation letter, while those who are illiterate it will be necessary to read for them and that the nurse/ doctor/ researcher sign on their behalf when they have orally approved participation. If they are willing to participate or hear more about the study, but due to spare time when meeting you it is not possible to read the information/ invitation and obtain the informed consent, the researcher will take care of this when they are willing to meet her.

Please keep in mind that the client has the right to refuse to participate in the study, and the patients needs to be informed that they can withdraw from the study without any consequences for treatments. The data is confidential, will be stored in personal computer

protected with password and will not be exposed to any third part. Hard copy (paper) documents such as signed consents will be kept in a secured locked cabinet.

In addition to this information/invitation letter, there is an information letter to the patient and an informed consent letter is attached.

Thank you in advance

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ANNEX- II: Information sheet to the participants of the study

Request to participate in the project "Assessing quality of life among Ethiopian women with breast cancer who are patients at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia 2015"

The purpose of this study is to assess the quality of life of patients with breast cancer at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia. The research is a master thesis in International Social Welfare and Health Policy at Oslo and Akershus University College of Applied Science, Oslo. Norway. The researcher and interviewer is an Ethiopian woman, who can speak Amharic, while her supervisor is a Norwegian professor. The study is approved both from the Tikur Anbassa specialized hospital Institutional Board as well as REK (Regionale Komiteer for Medisinskog Helsefaglig Forskningsetikk) in Norway, which is founded on the Norwegian law on research ethics and medical research.

You are invited to the study because you are a patient at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia.

Duration: 40 Minutes (the same day as you are at the hospital for treatment)

Procedure to be carried out: We will only interview you and there will not be any invasive procedure.

Risks associated with the study: Apart from the time you are going to use during the interview filling in the questionnaire together with the interviewer, there will not be any risk acquired by participating in the study.

Benefits of the study: Taking part in the study helps;

To improve the knowledge about quality of life of patients with breast cancer in Ethiopia

To provide basic information for health policy makers, administrators, researchers and for patients who are suffering from breast cancer.

Compensation- There will be no compensation

Confidentiality of the information: Personal information you are going to give during the data collection will be confidential. Your name will not be written in the questionnaire and once the data is entered into a computer, it will be coded and becomes unidentifiable. Information in the computer will be password protected. Hard copy (paper) documents such as consent and information forms will be kept in a secured locked cabinet.

Termination of the study: You will be recruited based on your willingness and without obligation to participate in the study. You have the right to withdraw from participating in the study whenever you want to (before completing the study). Participation in the study will have no implications for your relation and treatment at the hospital.

If you want to participate in the study you either sign the attached informed consent or you tell the nurse/ doctor or researcher that you are willing to participate (oral consent), and this person sign on your behalf.

Thank you in advance.

With kind regards

Meron Amare Bekele

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ANNEX III Consent form

I am willing to participate in the study "Quality of life in Ethiopian women with breast cancer who are patients at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia". (Circle either yes or no)

Yes

No

Tikur Anbassa Specialized Hospital oncology unit, Addis Ababa, Ethiopia

Date...

Signature …………………………………………

Signature of the person who recruited the respondent…………………………..

Title---

ANNEX IV: English version Questionnaire

The objective of this study is to assess the quality of life of patients with breast cancer at Tikur Anbassa Specialized Hospital, Addis Ababa, Ethiopia.

Instruction: -

Dear clients,

First I would like to thank you for your voluntary participation in this study. I politely requested that you respond to the interview accurately and I assure you that your response and identifying data will be kept confidential. The result of this survey will be useful for future planning of health service for breast cancer patients. Therefore; you are politely requested to give accurate information. Still you are free not to answer some of the questions if you are not interested.

PART ONE-SOCIO-DEMOGRAPHIC DATA

1. Age_____

2. Marital status

A. Never married

B. Married

C. Widowed

D. Divorced

E. Others (specify)--------------------

3. Educationallevel

A. No formal education

B. 6th grade and below

C. 7-9 grade

D. 10-12 grade

E. 12 grade and above

4. Occupational status

A. House wife

B. Government Employee

C. Merchant

D. Student

E. Dailylabor

F. Others (specify) ----------------

5. Average monthly income (in Birr)

A. <320

B. 320-500

C. 501-700

D. >701

6. When did you receive your first diagnosis of cancer? (Please specify years and months)

7. What type of treatment have you received?

A. Chemotherapy

B. Radiotherapy

C. Surgery

D. Chemotherapy, radiotherapy and surgery

E. Others(specify)----------------

PART TWO- THE QLQ-C30 VERSION 1.0 WITH FUNCTIONAL / SYMPTOM SCALES INDICATED

Please indicate the extent to which you have experienced these symptoms or problems during the past week.

	Not at All	A Little	Quite a Bit	Very Much
1.Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.Do you have any trouble taking a <u>long </u>walk?	1	2	3	4
3 Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4.Do you need to stay in bed or a chair during the day?	1	2	3	4
5.Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

6.Were you limited in doing either your work

or other daily activities?   1   2   3   4

7. Were you limited in pursuing your hobbies or other

   leisure time activities?   1   2   3   4

8. Were you short of breath?   1   2   3   4

9. Have you had pain?   1   2   3   4

10. Did you need to rest?   1   2   3   4

11. Have you had trouble sleeping?   1   2   3   4

12. Have you felt weak?   1   2   3   4

13. Have you lacked appetite?   1   2   3   4

14. Have you felt nauseated?   1   2   3   4

15. Have you vomited?   1   2   3   4

16. Have you been constipated?   1   2   3   4

During the past week:

17. Have you had diarrhea?   1   2   3   4

18. Were you tired?   1   2   3   4

19. Did pain interfere with your daily activities?   1   2   3   4

20. Have you had difficulty in concentrating on things,

   like reading a newspaper or watching television?   1   2   3   4

21. Did you feel tense?   1   2   3   4

22. Did you worry?   1   2   3   4

23. Did you feel irritable?   1   2   3   4

24. Did you feel depressed?   1   2   3   4

25. Have you had difficulty remembering things?   1   2   3   4

26. Has your physical condition or medical treatment

   interfered with your <u>family</u> life?   1   2   3   4

27. Has your physical condition or medical treatment

interfered with your <u>social</u> activities? 1 2 3 4

28. Has your physical condition or medical treatment

   caused you financial difficulties? 1 2 3 4

For the following questions please choose the number between 1 and 7 that best applies to you

29. How would you rate your overall <u>health</u> during the past week?

1 2 3 4 5 6 7

 Very poor   Excellent

30.   How would you rate your overall <u>quality of life</u> during the past week?

1 2 3 4 5 6 7

 Very poor   Excellent

Part Three- EORTC QLQ - BR23

Please indicate the extent to which you have experienced these symptoms or problems during the past week.

During the past week	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
31. Did you have a dry mouth?	1	2	3	4
32. Did food and drink taste different than usual?	1	2	3	4
33. Were your eyes painful, irritated or watery?	1	2	3	4
34. Have you lost any hair?	1	2	3	4
35. Answer this question only if you had any hair loss:				
Were you upset by the loss of your hair?	1	2	3	4
36. Did you feel ill or unwell?	1	2	3	4
37. Did you have hot flushes?	1	2	3	4
38. Did you have headaches?	1	2	3	4

39. Have you felt physically less attractive
    as a result of your disease or treatment?   1   2   3   4

40. Have you been feeling less feminine as a
    result of your disease or treatment?   1   2   3   4

41. Did you find it difficult to look at yourself naked?   1   2   3   4

42. Have you been dissatisfied with your body?   1   2   3   4

43. Were you worried about your health in the future? 1   2   3   4

During the past <u>four</u> weeks:

44. To what extent were you interested in sex?   1   2   3   4

45. To what extent were you sexually active?
    (with or without intercourse)   1   2   3   4

46. Answer this question only if you have been sexually
    active: To what extent was sex enjoyable for you? 1   2   3   4

During the past week:

47. Did you have any pain in your arm or shoulder?   1   2   3   4

48. Did you have a swollen arm or hand?   1   2   3   4

49. Was it difficult to raise your arm or to move
    it sideways?   1   2   3   4

  50. Have you had any pain in the area of your
    affected breast?   1   2   3   4

51. Was the area of your affected breast swollen?   1   2   3   4

52. Was the area of your affected breast oversensitive?   1   2   3   4

53.   Have you had skin problems on or in the area of
    your affected breast (e.g., itchy, dry, flaky)?   1   2   3   4

ANNEX V- Information sheet to participants (Amharic version)

አባሪ 1፤ የተሳታፊዎች መረጃ ቅጽ

የዚህ ጥናት ዓላማ በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል የጡት ካንሰር ላለባቸው ህመምተኞች ሲሆን፣ ይህም ጥናት የሚያተኩረው የጡት ካንሰር ላለባቸው ህመምተኞች የኑሮ ሁኔታ ጥራት ላይ ነው። ይህ ጥናት የማስተርስ ፕሮግራም በ `` International Social Welfare and Health Policy at Oslo and Akershus University College of Applied Science, Oslo. Norway `` መመረቂያ ፅሁፍ ነው። የጥናቱ ባለቤት አማርኛ ተናጋሪ ኢትዮጵያዊ ስትሆን ተቆጣጣሪዋ የኖርዌይ ፕሮፌሰር ነች። ጥናቱ በፍቃድ ሰጪ አካላት ወይም (Tikur Anbassa specialized hospital Institutional Board እና REK (Regionale Komiteer for Medisinskog Helsefaglig Forskningsetikk) ተረጋግጧል።

በዚህ ጥናት ላይ እንዲሳተፉ የተጋበዙት በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል፣ አዲስ አበባ፣ ኢትዮድያ ታካሚ ስለሆኑ ነዉ።

የሚፈጀው ጊዜ: 40 ደቂቃ ነው (ሆስፒታል በመጡበት በዛዉ ቀን)

1. አሁን የምናደርገው ቃለ ምልልስ ሲሆን በአካልዎት ላይ የሚደረግ ምንም ዓይነት ነገር አይኖርም።

2. በዚህ ጥናት በመሳተፍዎ ጊዜዎትን ከመሻማት ውጪ ምንም ዓይነት ጉዳት አይደርስብዎትም።

3. የጥናቱ ጠቀሜታ

3.1 የጡት ካንሰር ስለለባቸው ህሙማን የኑሮ ሁኔታ ጥራት እዉቀት መጨመር

3.2 የዚህን ጥናት ውጤትም ሌሎች ጤና በተመለከተ መተዳደሪያ ደንብ ለሚያወጡ ግለሰቦች፣ አስተዳደሪዎች፣ ጥናትን ለሚያከናውኑ ግለሰቦችና በተለይም በጡት ካንሰር ለሚሰቃዩ ህሙማን መሠረታዊ የሆነ መረጃ ይሰጣል።

4. ይህ ጥናት ምንም ዓይነት የተሳታፊነት ክፍያ አይሰጥም።

5. የመረጃው ምስጢር አጠባበቅ

ይህ የሚሰበሉን ግለሰባዊ መረጃ ምስጢራዊነቱ የተጠበቀ ነው። ይህም መረጃ በኮምፒዩተር በምስጢር ከተመዘገበ በኋላ ስምዎት አይጠቀስም። እናም በምንም ዓይነት መንገድ ሊታወቅ አይችልም። በኮምፒዩተር ዉስጥ ያለዉ መረጃም በምስጢር ኮድ ታስሮ ይቀመጣል። ወረቀቶቹም በምስጢር ይቀመጣሉ።

6. ከተሳታፊነት ስለመቆረጥ

ይህን መረጃ የሚሰጡት ያለምንም ግዴታ በሙሉ ፈቃደኝነትዎ ነዉ። ጥናቱ ከተጀመረ በኋላ በማንኛውም ጊዜ ተሳትፎዎን የማቋረጥ ሙሉ መብት ይኖርዎታል። በጥናቱ ላይ መሳተፍ በሆስፒታሉ ካለዎት ግንኙነት ጋር ተፅእኖ የለዉም

በጥናቱ ላይ ለመሳተፍ የሚፈልጉ ከሆነ ወይ የተያያዘውን መረጃ ስምምነት መፈረም ወይም ደግሞ መስማማትዎን ለነርስ / ሐኪም ወይም ጥናቱን ለሚሰበስበዉ ሠዉ ይንገሩ እነሱም በርስዎ ስም ይፈርማሉ።

ከምስጋና ጋር

ሜሮን አማረ

የስልክ ቁጥር 0912493454

ኢ.ሜይል meri2024@yahoo.com

ANNEX VI Consent form (Amharic version)

አባሪ 2፤ *ፈቃደኝነትን የሚያረጋግጥ ቅጽ*

እኔ በጥቁር አንበሳ ሆስፒታል የሚታከሙ የጡት ካንሰር ያለባቸው ህመምተኞች የኑሮ ሁኔታ ጥራት ጥናት ላይ ለመሳተፍ ፍቃደኛ ነኝ (አዎ ወይም የለም የሚለዉን ያክብቡ)

1. አዎ

2. የለም

በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል ካንሰር ዩኒት፣ አዲስ አበባ፣ ኢትዮድያ

ቀን ....

ፊርማ ....

የምስክር ሰጪ ፊርማ .... የጠያቂዉ ሰው ፊርማ ....

ማዕረግ -- -

ANNEX VII: Amharic version Questionnaire

አባሪ 3፤ የመጠይቅ ቅጽ

<u>መመሪያ፤</u>

የዚህ ጥናት ዓላማ በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል የጡት ካንሰር ላለባቸው ህመምተኞች ሲሆን፣ ይህም ጥናት የሚያተኩረው የጡት ካንሰር ላለባቸው ህመምተኞች የኑሮ ሁኔታ ጥራት ላይ ነው። የተከበራችሁ የጡት ካንሰር ያለባችሁ ህመምተኞች ለቃለ መጠይቁ ፈቃደኛ በመሆናችሁ በቅድሚያ አመሰግናለሁ። በመቀጠል ይህንን ቃለ መጠይቅ በትክክል እንድትመልሱልኝ ስጠይቅ የምትመልሱት መልስም ሆነ የእናንተ ማንነት በምንም ዓይነት ሁኔታ ለዖትኛውም ወገን እንደማይገለጽ ቃል እገባላችኋለሁ። የዚህ ቃለ መጠይቅ ውጤት ለወደፊ የጡት ካንሰር ላለባቸው ህመምተኞች ጠቃሚ ነው። ስለሆነ ትክክለኛውን መልስ በመስጠት እንድትተባበሩን በትህና እጠይቃለሁ። ጥያቄዎቹን ያለመመለሥ መብትዎ የተጠበቀ ነው።

ክፍል 1፤ ግለሰባዊ መረጃዎች

1. ዕድሜ _____

2. የጋብቻ ሁኔታ

   ሀ/ ያላገባች

   ለ/ ያገባች

   ሐ/ በሞት የተለያየች

   መ/ በፍች የተለያየች

   ሠ/ ሌሎች..........

3. የትምህርት ደረጃ

   ሀ/ መደበኛ ትምህርት ያልገባች

   ለ/ 6ኛ ክፍልና ከዚያ በታች

   ሐ/ ከ7ኛ-9ኛ ክፍል

   መ/ 10-12 ክፍል

ሠ/ 12ኛ ክፍልና በላይ

4. የሥራ ሁኔታ

ሀ/ የቤት እመቤት   ለ/ የመንግሥት ሠራተኛ   ሐ/ ነጋዴ

መ/ ተማሪ   ሠ/ የቀን ሠራተኛ   ረ/ ሌላ _____

5. አማካይ የወር ገቢ

ሀ/ ከ320 በታች   ሐ/ ከ501 - 700

ለ/ ከ320 - 500   መ/ ከ701 በላይ   ሠ/ ምንም ገቢ የሌላቸው

6. ለመጀመሪያ ጊዜ የጡት ካንሰር እንዳለብዎ የተነገረዎ መቼ ነው? /እባክዎ በዓመትና በወር ይግለጹ/

7. ለጡት ካንሰርዎ ምን ዓይነት ህክምና እየወሰዱ ነው?

ሀ/ ኬሞ ቴራፒ

ለ/ የጨረር ህክምና

ሐ/ ቀዶ ጥገና

መ/ ሌሎች _____

EORTC QOL C-30 Amharic version

	በጭራሽ	በትንሹ	በማኮ	በጣም በብዛት
1. እንደ ከባድ ዘንቢል ወይምሻንጣማ ከምየ መሳሰሉ ጉልበት የ ሚጠይቁ እንቅስቃሴዎችን ለማድረግ ችግር አለብዎት?	1	2	3	4
2. ረዥምየ እግር ጉዞ ለማድረግ ችግር አለብዎ?	1	2	3	4
3. ከቤትዎ ወጫአ ጨፎ የ እግር ጎዞ ለማድረግ ችግር አለብዎ?	1	2	3	4
4. በህ መሟዎ የ ተነ ሳ በቀን አልጋ ላይ ወይምወንበር ላይ ሆነ ዉረዘ ምላለ ሰዓት ያሳልፋሉ?	1	2	3	4
5. ሲማ ቡ፣ ሲለብሱ፣ ሲታጠቡ ወይምሽንት ቤት ሲጠቀመጃ ገዛ ያስፈልግዎታል?	1	2	3	4

ባለፈው ሳምንት ወስጥ-	በጭራሽ	በትንሹ	በማኑ	በጣም በብዛት
6. ስራዎትን ወይንም የዕለት ተለት እንቅስቃሴዎትን ለማክናወን ተገድበው ነበር?	1	2	3	4
7. በትርፍ ጊዜ የሚከናወኑ ስራዎችን ወይንም ሌሎች የማዝናኛ ጊዜዎችን ለማሳለፍ ገድበው ነበር?	1	2	3	4
8. ሲተነፍሱ የትንፋሽ ማጠር አጋጥሞት ነበር?	1	2	3	4
9. የህመምስ ማቃነበረብዎ?	1	2	3	4
10. ከውትሮውየተለየ ዕረፍት አስፈልጎዎት ነበር?	1	2	3	4
11. የዕንቅልፍ ችግር ነበረብዎ?	1	2	3	4
12. አቅምያንስዎትነበር?	1	2	3	4
13. የምግብ ፍላጎትዎ ቀንሷል?	1	2	3	4
14. የ ማቅለሽለሽ ስማቃነበረብዎ?	1	2	3	4
15. አስ ማጄሶዎት ነበር?	1	2	3	4
16. የሰገራ ድርቀትነ በረብዎ?	1	2	3	4
17. ተቅ ማጡነ በረብዎ?	1	2	3	4
18. የድካምስ ማቃነ በረ ዎ?	1	2	3	4
19. ህመምየ ዕለት ተ ዕለት እንቅስቃሴዎትን ያውክብዎነ በር?	1	2	3	4
20. አንድአንድነ ገሮችን ትኩረት ስጥተውለ ማስራት ያውክዎት ነ በር (ለምሳሌ፤ ጋዜጣ ለ ማን በብ፣ ራዲዮ ለ ማጀ ማጥ)?	1	2	3	4
21. የውጥረት ስ ማቃ ነ በረብዎ?	1	2	3	4
22. የ ሚጨ ቅ ስ ማቃ ነ በረብዎ?	1	2	3	4
23. የ ማ ጨ ጨስ ማቃ ነ በረብዎ?	1	2	3	4
24. የ ሚደበር ስ ማቃ ነ በረብዎ?	1	2	3	4
25. ነ ገ ሮችን የ ማስታወስ ችግር ነ በረብዎ?	1	2	3	4
26. አካላዊ ሁኔ ታዎ ወይምየ ሚታተሉት ህክምና በ ቤተሰባዊ ሀይዎትዎ ላይ ያሳደረውተጽዕኖ ነ በር?	1	2	3	4

27. የጤፃዎ ሁኔታ ወይምየ ሚከታተሉት ህክምና በማህበራዊ ሕይወትዎ
    በማፀርጉት እንቅስቃሴዎ ላይ ያሳደረውተጽዕኖ ነበር?   1   2   3   4

28. የጤፃዎ ሁኔታ ወይምየ ሚታተሉት ህክምና ገንዘብእንዲያጥሩዎ   1   2   3   4
/እንዲቸግሮዎ/አድርጓል?

ለሚከተሉት ጥያቄዎች ከ 1-7 ካሉት ቁጥሮች ወስጥእርስዎን በደንብየ ማ ልጽዎን አንዱን ቁጥር ያክብቡ

29. በአጠቃላይ ባለፈውሳምት የነ በረዎን የ ጤነ ት ሁኔ ታ እንዴት ይመዝኑታል?

1   2   3   4   5   6   7

በ ጣምመጥፎ   እ ጅግ በ ጣምጥሩ

30. በአጠቃላይ ባለፈውሳምት የነ በረዎን የ ኑሮ ሁኔ ታ ጥራት እንዴት ይመዝኑታል?

1   2   3   4   5   6   7

በ ጣምመጥፎ   እ ጅግ በ ጣም ጥሩ

EORTC QLQ - BR23

ባለፈውሳምንት ወስጥ-	በፍፁ ሽ	በትንሹ	በማሉ	በጣ ም
31. አፍዎ ይደርቅበት ነ በር?	1	2	3	4
32. የ ምግብና የ ማከቱ ጣዕ ምከ ወትሮ ተለውጦባዎት ነ በር?	1	2	3	4
33. አይንዎትን የ ማማጥ፣ የ መቆጥቆጥ ወይምእንባ የ ማቅረር ስ ሜቁ ነ በረ ብዎ?	1	2	3	4
34. ፀ ጉርዎ ሳስቶ ወይምተሜጸሎነ በር?	1	2	3	4
35. ይህንን ጥያቄ ፀ ጉርዎ ሳስቶ ወይምተሜጸሎከነ በረ ብቻ ፀ ጉርዎ በ ማሳቱ ወይምበ መሟ ጡተበ ሳጭቶውነ በር?	1	2	3	4
36. የ ህ መምወይምሕቀ ኛ ያለ ማሆን ስ ሜቁ ነ በረ ብዎት?	1	2	3	4

37. ፈትዎ አካባቢ ድንገተኛ መቁት ማለብእና ማቃጠል ተሰምቆዎት ነበር?	1	2	3	4
38. ራስ ምታት ነበረብዎ?	1	2	3	4
39. በሕመምዎ ወይምበሕክምና ውጤክንያት ዓይን የማይስቡሰው እንደሆኑ ዓይነ ስሜቱ ተሰምቆዎት ነበር?	1	2	3	4
40. በህመምዎ ወይምበህክምናዉ ምክንያት ሴትነ ትዎ ተሰምቆዎት ነበር?	1	2	3	4
41. ራቁት ሰውነ ትዎን ማት ይቸግርዎ ነበር?	1	2	3	4
42. በሰውነ ትዎ አቁምያልረኩበት ጊዜነ በር?	1	2	3	4
43. ለወደፈት ጤን ትዎ ይጨ..ቁ ነበር?	1	2	3	4

ባለፉት አራት ሳምንታት ዉስጥ-

	በጭ ራሽ	በትንሹ	በማኩ	በጣ ም
44. ለፆታዊ ግንኙነ ት ፍላጌትዎ ምን ያህል ነበር?	1	2	3	4
45. ፆ ታዊ ግን ኙ ት ላይ ምን ያክል ተሳታፊ ነ በሩ? (ከግብረ ስጋ ወይምካለ ግብረ ስጋ ግንኙነ ት)	1	2	3	4
46. ይህንን ጥያቄ ፆ ታዊ ግንኙነ ት ላይ ተሳታፈ ከነ በሩ ብቻ ይማእሱ- ፆ ታዊ ግን ኙ ት ቱ ለእርስዎ ምን ያህል አስደሳች ነ በር?	1	2	3	4
47. ክንድዎትን ወይምትከሻዎትን ህሙተሰምቆዎት ነ በር?	1	2	3	4
48. ክንድዎ ወይም እ ጅዎ ት አብጦ ነ በር?	1	2	3	4
49. ክንድዎትን ለማነሳት ወይምወደ ጎን ለማነቀሳቀስ ይቸግሮት ነ በር?	1	2	3	4
50. በበሽታ በተጠቃዉጧዉ አካባቢ ህሙምይሰማዎት ነ በር?	1	2	3	4
51. በበሽታ የተጠቃዉጧዉ አካባቢ አብጦ ነ በር?	1	2	3	4
52. በበሽታ የተጣዉጧዉ አካባቢ በትንሹ ሲነ ካ ከባድ ስሜ ነ በረዉ?	1	2	3	4
53. በበሽታ በተጠቃዉጧዉ አካባቢ የቆዳ ችግር ነ በር (ምሳ ሌ፣ ማስከክ፣ የመ..ረቅ፣ የማ..ላጥ)?	1	2	3	4

Ethical clearance from Regionale Komiteer for Medisinskog Helsefaglig Forskningsetikk

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:		Vår dato:	Vår referanse:
REK sør-øst	Tor Even Svanes	22845521		09.10.2015	2015/1568/REK sør-øst C
				Deres dato:	Deres referanse:
				18.08.2015	

Vår referanse må oppgis ved alle henvendelser

Amy Østertun Geirdal
Høgskolen i Oslo og Akershus

2015/1568 Livskvalitet hos etiopiske kvinner med brystkreft

Forskningsansvarlig: Høgskolen i Oslo og Akershus
Prosjektleder: Amy Østertun Geirdal

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtet 17.09.2015. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektomtale
Forskningen vil gi ny kunnskap om heslerelatert livskvalitet hos etioiske brystkreftrammede kvinner. I tillegg til spørsmål om livskvalitet vil det bli innhentet demografiske og sykdomsrelaterte spørsmål som lengde på diagnose og type behandling. Det vil bli anvent kvantitativ forskningsmetode ved å anvende selvutfyllende spørreskjemaer. Imidlertid er en stor del av den etiopiske befolkningen analfabeter, og både informasjonsbrev, informert samtykke vil bli lest for respondentene som sier ja til å delta, og spørsmålene i spørreskjemaet vil bli gitt som intervju hvor spørsmålene leses, svaraltarativene klargjøres og respondenten svarer på disse. Det er ikke gjort en tilsvarende undersøkelse, og anses viktig

Vurdering
Komiteen viser til søknadens del **3- Informasjon, samtykke og personvern,** hvor det angis: *Alle inviterte polikliniske pasienter som takker ja til å delta i studien vil signere informert samtykke. For de som er analfabeter vil informert samtykke sikres ved at informasjonsbrev/invitasjon til å delta i studien og det informerte samtykket leses og sikres muntlig at respondenten har forstått. Hvis vedkommende samtykker vil hennes navn skrives på samtykke skjemaet samt at intervjuer bekrefter med egen signatur at oralt samtykke er gitt.*

Fremgangsmåten utdypes videre: *Når pasientene kommer til sykehusets poliklinikk har de avtale med sykepleier eller lege som informerer om studien og stiller spørsmål om den aktuelle pasienten vil delta, eventuelt deler ut informasjonsskriv. Forsker vil oppholde seg i poliklinikken og møte pasienten samme dag.*

Det dreier seg dermed om et svært klinikknært forskningsprosjekt, hvor pasientene også rekrutteres i en direkte behandlingsmessig setting. For pasientene kan det muligens, med en slik løsning, være vanskleig å skille de ulike rollene helsepersonellet har, fra hverandre. Komiteen forutsetter at forsker har høy bevissthet knyttet til denne potensielle rollesammenblandningen, og særskilt understreker overfor pasientene at deltakelse i forskning er frivillig.

Komiteen forutsetter videre at den skisserte samtykkeinnhentingen er forenelig med etiopisk regelverk, og

godkjent av den etiopiske etiske komiteen.

Spørsmålene 44 til 46 i vedlagte spørreskjema omhandler seksuell funksjon, og selv om spørsmålene er berettiget i lys av et livskvalitetsperspektiv, kommer de ganske brått på. Komiteen krever derfor at forsker sørger for en form for overgang mellom spørsmålene, for eksempel ved at man forbereder pasienten på at man nå skal snakke om seksualitet.

Ut fra dette setter komiteen følgende vilkår for prosjektet:

1. Forsker må være bevisst rekrutteringen i en behandlingssituasjon, og understreke frivilligheten av å delta for pasientene.
2. Pasientene skal forberedes i forkant av spørsmål om seksualfunksjon.

Vedtak
Prosjektet godkjennes under forutsetning av at ovennevnte vilkår oppfylles, jf. helseforskningslovens §§ 9 og 33.

I tillegg til vilkår som fremgår av dette vedtaket, er tillatelsen gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden og protokollen, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Tillatelsen gjelder til 31.12.2016. Av dokumentasjonshensyn skal prosjektopplysningene likevel bevares inntil 31.12.2021. Opplysningene skal lagres avidentifisert, dvs. atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Komiteens avgjørelse var enstemmig.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK sør-øst på eget skjema senest 01.03.2017, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK sør-øst dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK sør-øst. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Britt-Ingjerd Nesheim
prof.dr.med
leder REK sør-øst C

Tor Even Svanes
seniorrådgiver

Kopi til:
Dag.Jenssen@hioa.no,
Høgskolen i Oslo og Akershus ved øverste administrative ledelse: postmottak@hioa.no

Ethical clearance from Addis Ababa University, College of Health Sciences Institutional Review Board

ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES (IRB)
አዲስ አበባ ዩኒቨርስቲ ጤናሳይንስ ኮሌጅ
Institutional Review Board

IRB's Decision

Meeting No: 007/2016   Date: August, 2016
Protocol number: 036/16/Radioth   Assigned No.

Protocol Title: Assessing Quality of life among patients with breast cancer at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia	
Investigators:	Meron Amare, Amy Østertun Geirdal, Aynalem Abraha
Institute:	College of Health Sciences, AAU
Elements Reviewed (AAUMF 01-008) :	☑ Attached ☐ Not attached
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:
Decision of the meeting:	☑ Approved ☐ Approved with Recommendation ☐ Resubmission ☐ Disapproved

I. Elements approved-
    1. Protocol Version No: 02
    2. Protocol Version Date: 24/07/2016
    3. Informed consent Version No. : 02
    4. Informed Consent Version Date : 24/07/2016
II. Obligations of the PI-
    1. Should comply with the standard international & national scientific and ethical guidelines
    2. All amendments and changes made in protocol and consent form needs IRB approval
    3. The PI should report SAE within 10 days of the event
    4. End of the study, including manuscripts and thesis works should be reported to the IRB
III. TO NERC ☐

Institution Review Board (IRB) Approval: Period from 02/09/2016 to 01/09/2017
Follow up report expected in

3 Months ___   6 months ____   9 months ✓ ____ one year ____

Chairperson, IRB
Dr. Yimtubezenash Woldeamanuel
Signature
Date