HEALTH RELATED QUALITY OF LIFE OF BREAST CANCER PATIENTS AT KENYATTA NATIONAL HOSPITAL

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MBChB

A Dissertation Submitted In Part Fulfillment of the Requirements for Award of the
Master of Medicine in Internal Medicine of the University of Nairobi

DECLARATION

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

Signed........../...

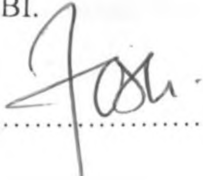DR. SYBIL K. NAKITARE
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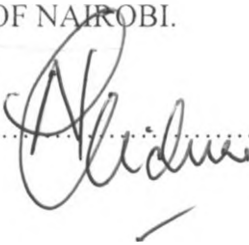UNIVERSITY OF NAIROBI.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

AIDS	-	Acquired Immunodeficiency Syndrome
BREF	-	Biomedical Research and Education Foundation
CaBr	-	Cancer of the breast
ECOG	-	Eastern Co-operative Oncology Group
EORTC	-	European Organization for Research and Treatment of Cancer
FACT-G	-	Functional Assessment of Cancer Therapy General
FLIC	-	Functional Living Index-Cancer
HER-2	-	Human Epidermal Growth Factor Receptor 2
HIV	-	Human Immunodeficiency Virus
KEMRI	-	Kenya Medical Research Institute
LHRH	-	Luteinizing Hormone Releasing Hormone
MRI	-	Magnetic Resonance Imaging
QoL	-	Quality of Life
QLQ	-	Quality of Life Questionnaire
PTEN	-	Phosphate and Tensin Homolog
SD	-	Standard deviation
TNM	-	Tumour, Nodes, Metastasis
USA	-	United States of America
WHO	-	World Health Organization

ABSTRACT

Background: Breast cancer is a leading cause of cancer-related morbidity and mortality. The diagnosis and treatment of breast cancer affects quality of life of patients, especially in our set-up in Kenya where majority of breast cancer patients are relatively young. There are several interventions that have been shown to improve quality of life in breast cancer patients.

Objective: We set out to determine the health-related quality of life of breast cancer patients receiving cancer-specific treatment at the Haemato-oncology clinic and Cancer Treatment Centre of Kenyatta National Hospital.

Methods: The study is a cross-sectional descriptive study carried out at the Haemato-oncology clinic and Cancer Treatment Centre of Kenyatta National Hospital over a 4 month period. Adults over the age of 18 years who had tissue diagnosis of breast cancer were interviewed using EORTC QLQ-C30/BR23, a validated tool for measuring quality of life in cancer patients.

Results: A total of 142 patients (139 female and 3 males) were studied, with a mean age of 49.4 years (range 25-73). The mean scores for global quality of life and other domains of quality of life screened for are as follows (possible scores range 0-100): Global quality of life 65.5 (SD 19.9), physical function 84.5(SD 14.2), role function 79.5(SD 27.3), emotional function 86.4(SD 17), cognitive function 83.6(SD 23.1), social function 89(SD 19.1), future perspective 66.9 (SD 34.2), and sexual function 19.4 (SD 25.9). Mean scores for the domains of symptom scales were as follows: fatigue 22.1(SD 21.2), upset by hair loss 23.1(SD 35.9), pain 19.4(SD 25.3), and financial difficulty 71.8(SD 33.3). Marriage and having an education were associated with better role (p 0.001 and p 0.001 respectively) and cognitive function (p 0.005 and p 0.004 respectively).

Conclusion: Quality of life and functional scale scores in these breast cancer patients is good, with low symptom burden. However, they have low sexual function and high financial burden.

1.0   BACKGROUND

Cancer is one of the leading causes of morbidity and mortality worldwide. More than 24 million people in the world are living with a malignancy and global incidence is estimated to be 10 million new cases per year. Predictions suggest that this figure could rise by 50% and reach 16 million new cases per year by 2020. Africa contributes 5.6% of the global cancer burden (this could be an underestimation as a result of under-diagnosis and under-reporting).The World Health Organization estimates the incidence of cancer in Kenya to be 12,000 per 100,000 per year.[1].

Cancer has the greatest economic impact out of all the diseases in the world[2], exceeding that of heart disease, stroke and HIV/AIDS. Globally, lung cancer, colorectal cancer and breast cancer have the greatest economic impact.

The five most common types of cancer in the world are of the lung, breast, colorectum, stomach and prostate. Breast cancer and prostate cancer are the most common in females and males respectively[1].

The Nairobi Cancer Registry[3] located at KEMRI captures data from Nairobi and its environs. Its most recently published report contains data from between 2000 and 2002. For females, cancer of the breast, cancer of the uterine cervix, oesophageal cancer and stomach cancer were reported as the most common in that order. Breast cancer is seen from as early as 30 to 34 years with a peak at 40 to 55 years.

The Eldoret Cancer Registry is located at the Moi Teaching and Referral Hospital which serves mainly the North Rift and Western provinces of Kenya. Tenge et al[1] analysed data from the registry from 1999 to 2006. Cancer of the cervix was reported as most common in females, followed by that of the breast.
Currently, there is no national cancer registry in Kenya.

The goals of cancer treatment are to reduce mortality and morbidity. Reduction in morbidity is achieved by killing or controlling cancer cells and preventing recurrence. Reduction in morbidity involves alleviation of symptoms, and allowing patients to be as functional as possible – this is where quality of life comes in.

WHO defines quality of life[5] 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. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment. Quality of life is recognized as an outcome measure in treatment and in clinical trials, as well as an independent prognostic indicator. It helps in analysis of quality of healthcare and in identifying areas to improve.

2.0 CANCER OF THE BREAST

Breast cancer is the result of malignant proliferation of the epithelial cells lining the ducts or lobules of the breast.

2.1 Epidemiology of breast cancer

Cancer of the breast is predominantly a disease of females, with a male to female ratio of 1:100[6]. It is the second most common cause of cancer death in the world, after cancer of the lung[1]. Globally, it is the most common cause of death in women aged between 44 and 55 years. There were more than 1 million new cases of breast cancer worldwide in 2008. The disease is more common in North America and Europe and less common in Africa and Asia. Incidence in the United States is estimated at 100 persons per 100,000 per year. In these Western countries however, a plateau and apparent decline in incidence and mortality from breast cancer has been noted[7]. It is most likely due to aggressive screening, diagnosis and treatment. Incidence in Kenya is estimated to be 23.9 per 100,000 per year[1]. Despite the lower burden, developing countries, particularly Africa, have a higher morbidity and mortality due to breast cancer. The reasons for this include

late presentation of disease, and differences in biology of cancer affecting members of the black race (more aggressive forms of the disease affect those of African descent)[8].

In Kenya, breast cancer is responsible for 24.8% of the cancer burden in women[3]. This makes it the most common cancer in this country.

2.2   Risk factors for developing cancer of the breast

Increasing age is associated with increasing risk of breast cancer. Seventy five percent of all breast cancers in the USA are diagnosed in patients older than 50 years of age.[9] However, breast cancer is frequently diagnosed in young people in Africa and therefore, increasing age may not be as important a risk factor in our set-up.

Positive family history of breast cancer in a first degree relative imparts a 3 to 4 fold increased risk of developing breast cancer. Familial clustering has been reported in 5 – 8% of cases. Familial breast cancer syndromes and molecular anomalies have been documented. Mutations in genes such as BRCA1 and 2, p53 (Lifraumeni syndrome) and PTEN gene are high risk for breast cancer development. Between 50% and 60% of BRCA carriers develop breast cancer[10].

Prolonged exposure of the breast to endogenous oestrogen is another risk factor. These situations include early menarche, late menopause, late first pregnancy and nulliparity[11].

Environmental exposures to ionizing radiation, prolonged exposure to hormone replacement therapy or oral contraceptives, as well as alcohol consumption are all considered risk factors for developing breast cancer[12, 13].

Other risk factors are having breast lesions such as atypical hyperplasia and lobular carcinoma in situ[14].

2.3   Screening and diagnosis of breast cancer

Screening results in earlier diagnosis of breast cancer and therefore reduces morbidity and mortality.

Clinical breast examination by a health care practitioner is recommended every 3 years in women above the age of 40 years[15].

Regular screening mammography reduces mortality from cancer of the breast by up to 30% in those more than 50 years of age[16]. It can detect lesions two years before they become palpable. Sensitivity and specificity of mammography alone as a screening tool is 67% and 75% respectively. When combined with breast self examination, sensitivity of detecting lesions is increased to about 77%.

Definitive diagnosis is best made by following the triple diagnosis method: a combination of clinical findings, pathological findings and radiological findings. Up to 99% of all breast cancers will be correctly diagnosed by this method[17].

Clinical symptoms include breast specific complaints such as a palpable mass, change in breast contour, skin and/or nipple changes.

Pathological diagnosis is made by cytology of fine needle aspirate or histology of core biopsy. It is now less common to perform excisional biopsies as a diagnostic method. Part of pathological examination involves establishing the steroid hormone receptor status of the tumour and expression of the oncogene HER – 2/neu. There are 3 main molecular subtypes of breast cancer: luminal, basal, and HER2 positive. Luminal cancers are usually steroid receptor positive (either oestrogen or progesterone or both) and are subclassified into those that are HER-2 receptor positive(type B) and HER-2 receptor negative(type A).The basal subtype is negative for both hormone receptors and HER-2. It is more common in younger patients and more likely to affect women of African descent.[8, 18]

Magnetic resonance imaging (MRI) is an alternative imaging option[19]. It is usually reserved for those with high risk of breast cancer in whom other imaging has not provided conclusive information. Its disadvantage is the inability to detect microcalcification and its low specificity. When combined with clinical examination and mammography, MRI is 99% sensitive for detecting breast'cancer. It is however expensive and has a high rate of false positives.

2.4   Staging cancer of the breast

Breast cancer is considered as either early or late disease. Early disease corresponds to TNM stage 1 and 2 and includes carcinoma in situ and early invasive cancer. Late disease

corresponds to TNM stage 3 and 4 and includes metastatic disease (see appendix 2 and 3 for a detailed classification). Staging influences choice of treatment and prognosis. The 5-year survival rate of stage 1 cancer is 95-100% as opposed to 20% for stage 4 patients.[20] The aim of treatment in early stage disease is cure, while the aim in late disease is palliation.

2.5   Treatment of cancer of the breast

Treatment of early stage disease involves management of locoregional disease by surgery and radiotherapy, and systemic treatment using chemotherapeutic agents as well as endocrine and biologic therapy where indicated.

Breast conserving surgery is preferred where possible in early stage because it improves quality of life.[21] Ductal carcinoma in situ has a small risk of metastasis and thus breast conservation is most appropriate in its case. Conservation is contraindicated where there is multifocal disease, where achieving proper cosmesis is not possible and in pregnancy. Sentinel node sampling should be considered in early disease in centres with good pathology laboratory support. When breast conservation is not possible, mastectomy is performed. Modified radical mastectomy is currently the standard of care and includes axillary lymph node dissection.

Following surgery in early stage disease, adjuvant radiotherapy is indicated to reduce locoregional recurrence rates, increase survival and reduce mortality.[22] Patients receive 45 to 50 Grays of radiation therapy in daily 2 Gray fractions.

Adjuvant endocrine therapy[23] is offered to those with positive hormone receptors on histological evaluation (progesterone and oestrogen receptors). Tamoxifen has been widely used in this regard (for oestrogen and progesterone receptor positive tumours) for many years and has been shown to reduce disease recurrence. Other endocrine therapies in use include aromatase inhibitors such as anastrozole, which are usually used in post-menopausal women.[24,25]

Adjuvant systemic chemotherapy[23] is indicated in early stage disease. A summary of the agents that can be used are given in appendix 4.

For patients with HER-2/neu receptor positive, the biologic agent trastuzumab (Herceptin®) is available as additional systemic therapy[23].

Late disease stage 3 cancer can be approached by neoadjuvant chemotherapy, that is, preoperative chemotherapy to reduce tumour size followed by surgery. Radiotherapy thereafter is indicated in order to reduce chances of local recurrence, by upto 50% when combined with other treatment modalities such as hormone therapy[23].

Stage 4 disease is metastatic disease[26]. It is not all gloom and doom however, because breast cancer is highly treatable no matter the stage at diagnosis. Treatment at this stage is largely palliative and aimed at improving quality of life. The mainstay is chemotherapy. Endocrine therapy can also been used in this stage. The role of surgery, however, is limited; it is useful in toilette of an infected tumour mass, or in debulking a large tumour.

2.6   Tools for Measuring Quality of Life

Several tools have been developed for assessing quality of life. Some tools are general and can be applied to different disciplines. These include the World Health Organisation Quality of Life questionnaires (WHO- QOL100 and WHO - QOLBREF) and the Spitzer Quality of Life Index.

Questionnaires that have been developed specifically for assessing quality of life in cancer patients include :

1. Quality cf Life Questionnaire of European Organisation for Research and Treatment in Cancer (EORTC QLQ-C30 version 3)[27]
2. Functional Living Index – Cancer (FLIC)[28]
3. Functional Assessment of Cancer Therapy - General (FACT - G)[29]

The most commonly used instruments are the EORTC QLQ – C30 and the FACT – G.

EORTC QLQ – C30 version 3 is a validated questionnaire for assessing health - related quality of life in cancer patients in general. It was first used in 1993 and has since been applied in numerous clinical trials as well as non – trial studies world – wide, including studies on cancer'patients in Kenya[64]. Translations into various languages including Kiswahili are available. It measures functional scales (physical, role, cognitive, emotion, social), symptom scales (fatigue, pain, nausea, vomiting) and global health status (overall assessment).

3.0   LITERATURE REVIEW

3.1   Importance of Measuring Quality of Life in Cancer Patients

Quality of life is an independent prognostic indicator. Ganz et al[30] studied a cohort of lung cancer patients and found that quality of life early in disease was directly related to survival later on. All things equal, patients with better quality of life scores had better survival rates.

Quality of life is also useful as an endpoint for treatment options and is applied in clinical trials to assess treatment outcomes. Anderson et al[31] randomized patients with inoperable lung cancer into two groups. One received supportive care alone and the other received supportive care and gemcitabine. Quality of life was used as an endpoint and the group that received gemcitabine reported better quality of life.

Assessment of quality of life at all stages of cancer treatment can influence choice of treatment modalities. Silvestri et al[32] offered cancer patients different hypothetical treatment options with survival on the one hand and quality of life on the other. Many of the patients preferred improved quality of life to increased survival. They were willing to live a shorter but symptom free life, than an extended one without guarantee of reduced symptoms. This shows that survival and response rate are not the sole measures of successful management of cancer patients.

Detmar et al[33] showed that incorporating standardized quality of life assessment tools in daily clinical oncology practice facilitates discussion of issues affecting the patients. It helps to heighten physicians' awareness of their patients' quality of life and initiate communication.

3.2   Factors affecting quality of life in breast cancer

Quality of life in breast cancer is influenced by the disease itself[34] (direct disease effects, stage at diagnosis and clinical course), the treatment of the disease,[35] comorbidity,[36] age at presentation,[37] race or ethnicity and socioeconomic status[8].

Early stage breast cancer is potentially curable and its treatment options include breast conserving therapy.[21,23] In contrast, the chances of controlling locally advanced disease are poor. Therefore, patients who present earlier to hospital may have better quality of life, given the psychological aspects of knowing that there is hope of cure. Abinya et al found that 60% of breast cancer patients in Kenyatta National Hospital presented in late disease[38]. Maranga[39] found in his study in Kenyatta National Hospital that upto 81% of patients presented late to hospital, and some of the reasons for this late presentation included delayed seeking of health care, low socioeconomic status and lack of awareness.

Patterns of presentation and disease course are different in African people as opposed to Caucasians. In blacks, breast cancer occurs at an earlier age and takes on a more aggressive course.
Calleb et al[40] studied the patterns of breast cancer in Coast Provincial General Hospital in Mombasa, Kenya. One third of the population presented at an age below forty years.
The median age of breast cancer patients in the study by Maranga[39] was 40 to 50 years.
Mean age of presentation of breast cancer in a Nigerian survey was 42 years, far younger than in Caucasians[41].
In the United States, the mean age of presentation with breast cancer in African Americans is the fifth decade, while Caucasians present from the sixth decade[42]. Molecular biology patterns of the disease also show racial differences. The more aggressive 'triple negative' form (oestrogen receptor, progesterone receptor and HER-2 receptor negative) is more likely to affect blacks and appears in younger women[8,43].

Systemic chemotherapeutic agents used in breast cancer have acute side effects[35] including nausea, vomiting, and bone marrow suppression. Alopecia is greatly distressing to modern females because hair is part of their sexuality. Doxorubicin is used in many

regimens and has been associated with development of cardiomyopathy. There is also a small chance of developing other malignancies such as leukaemia following treatment.

Although in itself painless, radiotherapy has several side effects[35] that alter quality of life. Early on, these include fatigue, breast pain, swelling and skin desquamation. Later side effects that may be seen six months or more after radiotherapy include oedema of the breast, pain, fibrosis of breast and lung tissue, skin hyper-pigmentation, cardiac disease, and secondary malignancies.

Surgery has psychological side effects[44] because of the self image issues and psychological sexual dysfunction that arises from losing a breast. It may also result in lymphoedema and nerve damage depending on the extent of surgery[15].

Fertility is an important aspect of quality of life in individuals of reproductive age. The treatment of cancer using chemotherapeutic agents and radiotherapy can reduce the chances of having children. In breast cancer, alkylating agents such as cyclophosphamide have been associated with a greater risk of ovarian failure[46]. Regimens that use lower doses of these agents result in higher chances of fertility preservation. Hormonal therapy such as tamoxifen affects the menstrual cycle, and this may persist for years. Without any intervention, the incidence of live births in patients under 45 years of age who have been treated for cancer of the breast is as low as 3%[47]. Well equipped centres are now offering the option of harvesting and cryopreservation of mature oocytes, while research is ongoing in the area of cryopreserving ovarian tissue. In vitro fertilization after breast cancer is also an option[48]. At diagnosis, patients may be quick to accept whatever treatment that will save their lives, but later on, fertility becomes a major issue[49]. Health care providers would be more proactive about fertility preservation issues if they knew how much it affects quality of life.

Quality of life in cancer is also influenced by co – morbidities[36,50]. Some patients may have concurrent HIV, cardiovascular, renal or endocrine disease. These may be an effect of the cancer or an independent disease entity. Co – morbidities increase cost of illness, pill burden and thus reduce quality of life.

Quality of life issues and priorities of cancer patients and caregivers differ across cultures, ethnic groups and races. Murray et al[51] compared the issues affecting patients with advanced cancer in Meru, Kenya and in Lothian, Scotland. In Kenya, physical distress was the main complaint, with poorly controlled pain being an issue. Kenyan patients were concerned about finances – being unable to afford drugs and using up money that could pay school fees and meet other needs. Emotionally, Kenyans reported good community support and inner peace and acceptance of eventual death. Religion played an important role in psychological and emotional wellbeing. In Scotland, pain and money were not an issue since the health care services were free and efficient. However, many patients were worried about survival and had less religious and community support. In the United States, racial variations have been noted in the way that patients handle the end – of – life issues that arise with cancer[52,53]. Caucasians have been found to be more likely to write a will and would agree with physician-assisted suicide.[52] African – Americans may not write a will even in advanced disease.[52] They have been found to be more likely to favour treatments that are seen as 'heroic' by other races – such as nasogastric tube feeding and prolonged ICU care despite the obvious diagnosis.[52]

3.3 Interventions that can improve quality of life

Quality of life in cancer patients can be improved even in advanced disease.

Encouraging physical activity and supervised endurance training can improve physical functioning of cancer patients. Knols et al[54] carried out a meta – analysis of randomized clinical trials which aimed at improving physical function of breast cancer survivors. Patients were encouraged to increase their daily walking activity by having a goal of how many steps they took per day. Those who improved their daily step activity had improved physical function and subsequently improved quality of life.

Providing psychosocial support improves quality of life of cancer patients. Goodwin et al[55] studied the effect of supportive-expressive therapy on patients with metastatic breast

cancer. Patients who received group therapy had improved psychological symptoms, reported less pain, and had reduced distress.

In some advanced cancers, introducing early palliative care has been shown to improve quality of life. Temel et al[56] randomized patients diagnosed with small cell lung cancer. One group was offered early palliative care and their quality of life compared to a group that was not. The group that received early palliative care had higher quality of life scores, improved mood, and more frequent documentation of resuscitation preferences.

In Thailand, Thienthong et al[57] studied the effect of better pain management on health related quality of life. 76% of the patients had pain in 2 sites and an average score of 58.6% for quality of life. Improving pain management raised the score of quality of life significantly to 61% (p<0.001).

Quality of life of cancer patients can also be improved by use of complementary therapies. These are treatments that are used in conjunction with traditional cancer treatments to reduce symptoms and side effects. They include massage, acupuncture and mind – body interventions. Some of the techniques applied in mind – body interventions include meditation, self – hypnosis, yoga, tai chi, and aromatherapy. These techniques are pleasant, non – pharmacologic and do not interfere with cancer treatment itself. Acupuncture has been reported to be useful in reducing pain, neuropathy, nausea, vomiting as well as radiation - induced xerostomia[58]. Massage therapy reduces pain and alleviates anxiety, and is thought to reduce cortisol levels associated with anxiety[59]. Though not strictly considered a mind-body intervention, religion is important in quality of life of cancer patients. Spirituality is associated with better symptom control[60,61].
A controversial alternative therapy is the use of cannabis to control pain.[62] It has been authorized for use in cancer patients in the Netherlands and a few states in the USA.

3.4   Quality of life studies

Mwanda et al[63] assessed the quality of life of forty two male cancer in – patients in Kenyatta National Hospital. The tool used was Beck's Depression Inventory. He found levels of depression to be high and related to certain tumour types (gastrointestinal and haematologic) and lower level of education. Patients were affected mainly by their inability to work and effects on their financial status.

Kamau et al[64] studied the effect of diagnosis and treatment of inoperable cervical cancer on quality of life among women receiving radiotherapy at Kenyatta National Hospital. The EORTC QLQ-C30 tool was used. Almost half of the patients (46%) were less than 50 years of age. 47% of the patients reported high level of disruption in overall quality of life by scoring less than 4 out of a possible 7 points. Most patients were able to perform daily activities without assistance but about the same number were unable to cope with strenuous activity. Social support and involvement in leisure activity were reported as good by more than 61% of the patients.

Jaiyesimi et al[65] assessed health related quality of life and its determinants in Nigerian breast cancer patients undergoing radiotherapy. The EORTC QLQ-C30 tool was used to assess quality of life. Patients reported good physical, emotional and cognitive function but pain and fatigue affected their quality of life.

In Germany, Amdt et al[66] carried out a population based study on quality of life in women with breast cancer one year after diagnosis. The EORTC QLQ C30 tool was used. Fatigue explained 30% – 50% of variability within function scores and overall quality of life. Other symptoms such as pain, nausea, vomiting and side effects of therapy explained less than 5% of variability. Sociodemographic and clinical factors had little impact on quality of life in that study.

4.0   JUSTIFICATION

Breast cancer is common and on the increase in our population as an important non – communicable disease. In our set up, it affects young individuals at their economic and reproductive peaks and this trickles down to negatively impact on their dependents.

The treatment of breast cancer has an enormous impact on quality of life. In advanced disease, as most patients in Kenya present, cure is not the end-point of this treatment. It is therefore useful to establish the quality of life of our patients in order to provide information to policy makers on approach to treatment. Care providers can be sensitized on carrying out risk-benefit analyses and informing patients on treatment choices accordingly. Patients can also be provided with appropriate psychosocial and financial support from early on.

There is paucity of data pertaining to quality of life in patients with breast cancer in Kenya. This study will contribute to the health care information database.

5.0 RESEARCH QUESTION

What is the health-related quality of life of breast cancer patients at Kenyatta National Hospital?

6.0 OBJECTIVES

6.1 Broad Objective

To determine the health-related quality of life of breast cancer patients receiving cancer-specific treatment at the Haemato-oncology clinic and Cancer Treatment Centre of Kenyatta National Hospital.

6.2 Specific Objectives

1. To determine the socio-demographic characteristics, stage at diagnosis and cancer-specific treatment modalities of breast cancer patients.
2. To determine quality of life of breast cancer patients.
3. To correlate socio-demographic factors to quality of life parameters.
4. To correlate the stage of breast cancer at diagnosis to quality of life parameters.
5. To correlate modalities of breast cancer treatment to quality of life parameters.

7.0   METHODOLOGY

7.1   Study Design

This study was a cross-sectional descriptive survey.

7.2   Study Site

The study was carried out at the Haemato-oncology clinic and the Cancer Treatment Centre of Kenyatta National Hospital.

7.3   Study Population

The target study population was breast cancer patients receiving cancer-specific treatment at the Haemato-oncology and Cancer Treatment Centre of Kenyatta National Hospital.

7.3.1   Inclusion Criteria

The patients who were included were aged above 18 years, had given written informed consent and had a diagnosis of breast cancer by tissue histology or cytology. In addition, the included patients had to be ongoing or had to have just completed any standard modality of breast cancer treatment within the preceding six months.

7.3.2   Exclusion Criteria

The patients who either failed to give consent, or had known active psychosis, dementia or cognitive impairment were excluded from the study.

7.4   Sample Size

The following formula was used to calculate sample size:-

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

- n – sample size
- Z – 1.96 (95% confidence interval)
- σ- Standard deviation of the mean score of the global health status QoL = 24.2
- e- Desired level of precision of the variance = 4

By substituting into the formula, a minimum of 140 patients were required to estimate the average quality of life score among cancer patients.

The mean score of global health status was obtained from the scoring manual of the EORTC questionnaire. It provides an average score from numerous studies that have been carried out using this questionnaire. Some of the studies contributing to this score have been carried out in Africa.

7.5   Sampling Method

The sampling method that was employed was consecutive sampling.

7.6   Screening, Recruitment and Clinical Methods

The files of oncology patients presenting to the relevant clinics were screened for eligibility. Patients who were eligible were informed about the study, and those who provided consent were recruited into the study.

The pathological diagnosis of the cancer, stage at diagnosis, and history of all breast cancer specific treatment modalities were obtained from the file. Socio-demographic data including medical insurance status and parity of the patient was obtained from the patient by direct questioning as specified in the study proforma. Medical history, including the number of prior admissions and history of blood transfusions were also recorded. A routine physical examination was carried out, and ECOG scoring as an objective functional assessment was performed according to the specifications of the study proforma.

The EORTC QLQ-C30/BR23 questionnaire was interviewer - administered by the principal investigator and two trained research assistants (clinical officers) who were supervised. An English and Kiswahili version was available, but for patients who could not understand either, a translator who spoke the same language as the index case was used. Each patient was represented only once in the database.

7.7   Questionnaire: EORTC QLQ-C30 (VERSION 3)/BR23[27]

The EORTC QLQ-C30/BR23 is a 6-section questionnaire that addresses three main areas: functional scale, symptom scale and global health status. It addresses quality of life issues that are common to all cancer patients through the generic module, QLQ-C30, as well as those that are unique to breast cancer patients using the breast cancer module, BR23.

The functional scale assesses physical function, role function, cognitive function, emotional function and social function. Specific to breast cancer patients, sexual function, sexual enjoyment and body image issues are also assessed.

The symptom scale looks at common complaints that cancer patients present with including fatigue, pain, nausea and vomiting. Symptoms specific to breast cancer patients that are addressed include side effects of surgery, radiotherapy and chemotherapy.

For the functional and symptom scales, the patient responses ranged from a 'not at all' response to a 'very much' response which correspond to a score 1 to 4 respectively.

For global health status, patients rated their overall quality of life and health by choosing a number between 1 and 7.

A scoring manual from the developers of the questionnaire was used to guide on interpretation of the results.

Responses from the patients were in the form of a Likert scale. The raw scores from these responses were standardized using linear transformation methods so that final scores

ranged from 0 to 100. 100 corresponds to maximum score while 0 corresponds to minimum score.

Higher scores in the following categories correspond to a higher or better quality of life : Global Qol/health status, physical function, role function, cognitive function, emotional function, social function, body image, sexual function, sexual enjoyment, and future perspective.

Higher scores in the following categories correspond to a worse or lower quality of life: fatigue, nausea and vomiting , pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea, financial difficulties, systemic therapy side effects, breast symptoms, arm symptoms and upset by hair loss.

7.8 Flow chart

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┌─────────────────────┐
│ Oncology patient    │
│ 200                 │
└─────────────────────┘
          │
        [yes]
          │
          ▼
┌─────────────────────┐   [no]    ┌─────────────────────┐
│ Histologic evidence │─────────▶ │ Not eligible        │
│ of breast cancer    │           │                     │
│ 150                 │           └─────────────────────┘
└─────────────────────┘
          │
        [yes]
          │
          ▼
┌─────────────────────┐   [no]    ┌─────────────────────┐
│ On/6 months post    │─────────▶ │ Not eligible        │
│ any treatment       │           │ 50                  │
│ modality for CaBr   │           └─────────────────────┘
└─────────────────────┘
          │
        [yes]
          │
          ▼
┌─────────────────────┐   [no]    ┌─────────────────────┐
│ Consent given       │─────────▶ │ Not eligible        │
│ 142                 │           │ 8                   │
└─────────────────────┘           └─────────────────────┘
          │
        [yes]
          │
          ▼
┌─────────────────────┐
│ Recruited into study│
└─────────────────────┘
          │
        [yes]
          │
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┌─────────────────────┐
│ History, social and │
│ demographic data    │
└─────────────────────┘
          │
        [yes]
          │
          ▼
┌─────────────────────┐   [yes]   ┌─────────────────────┐
│ Physical Examination│─────────▶ │ EORTC QoL           │
│ and ECOG score      │           │ Questionnaire       │
└─────────────────────┘           └─────────────────────┘
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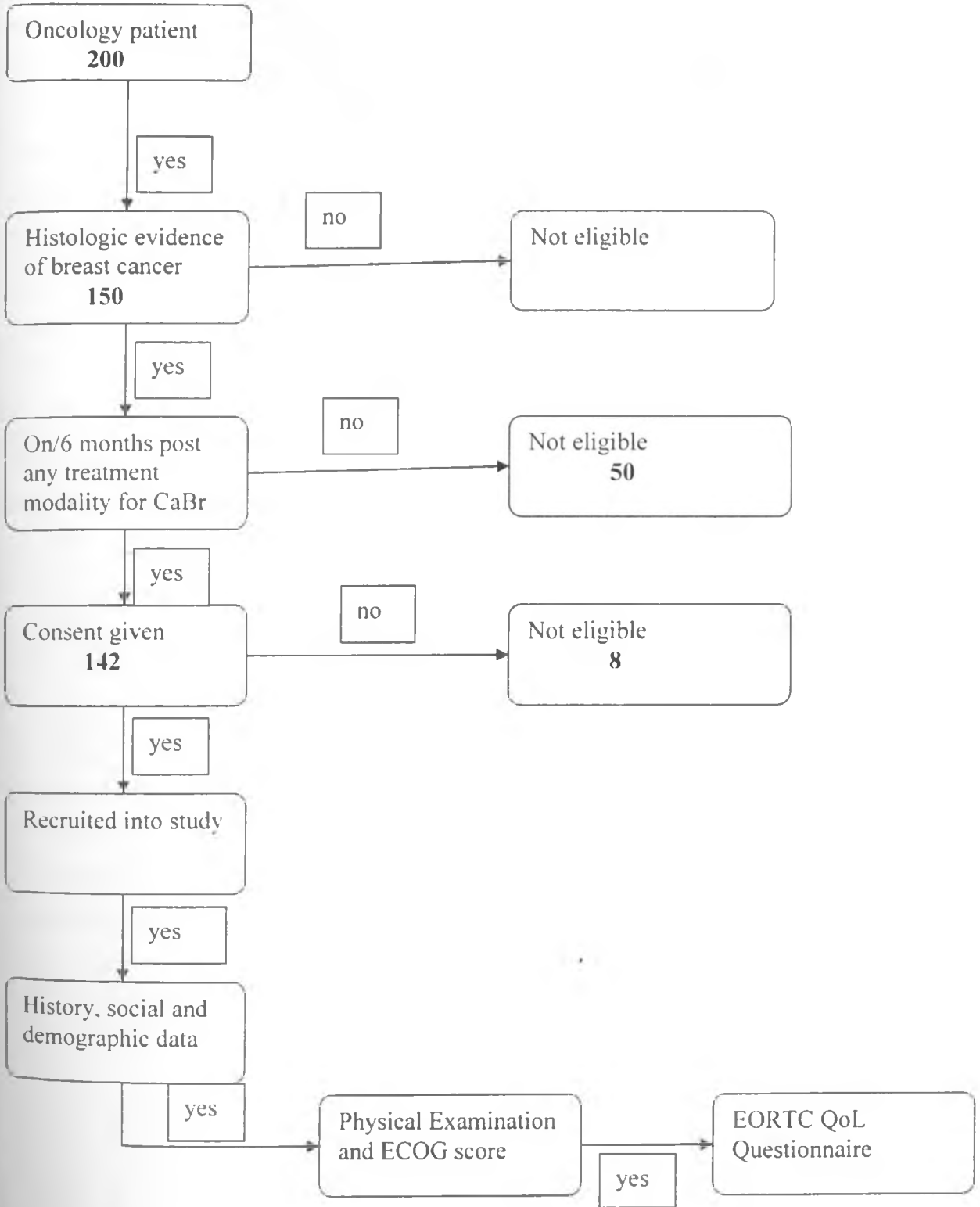
7.9   Data management and analysis

All data forms were stored in a secure cabinet accessible only to the principal investigator and the statistician. Data was cleaned, verified and entered daily into a password protected computer program (Microsoft Access®). Analysis was carried out using the Statistical Package for Social Scientists version 17.0.

Means, medians, modes and standard deviations were used to describe continuous data, while proportions were used to describe categorical data.

Quality of life of breast cancer patients was determined using the global health status, functional scales and symptom scales. The study population was categorized into 2 groups of >=50 and < 50 scores in global health status, functional scale and symptom scale. Relationship between age of the patients and quality of life was determined using Student's t-test. Marital status, education, religion, medical insurance, stage of cancer and type of treatment were associated with quality of life using χ^2 test. Patient's likelihood of presenting with worse or better quality of life was estimated using odds ratios. All the statistical tests were performed at 5% level of significance.

8.0   ETHICAL CONSIDERATIONS

Before commencing, permission to carry out this study was sought from the University of Nairobi's Department of Clinical Medicine and Therapeutics, as well as the Ethics and Research Committee of Kenyatta National Hospital/University of Nairobi. Only patients who gave informed consent were recruited into the study. No patient was coerced into participating. There was no discrimination against any patient who declined to participate. All information collected was treated as confidential. Any information that was deemed as important to the management of the patient was communicated to the primary health care provider. The cost of the study was met by the principal investigator.

9.0   RESULTS

Between June and September 2011, the files of two hundred breast cancer patients were consecutively sampled at the haemato-oncology clinic and cancer treatment centre of Kenyatta National Hospital. Fifty patients did not meet the inclusion criteria – forty patients were not on any treatment modality while ten patients did not have any documented breast cancer histology in their files. Out of those who met the inclusion criteria, eight patients declined consent, leaving one hundred and forty two (142) patients who were then recruited.

9.1   POPULATION CHARACTERISTICS

Table 1: Socio-demographic characteristics of the patients

Variable	Frequency (%) n=142
Age	
Mean (SD)	49.4 (10.2)
Min-Max	25.0-73.0
Gender	
Male	3 (2.1)
Female	139 (97.9)
Marital status	
Single	19 (13.4)
Married	96 (67.6)
Widowed	21 (14.8)
Divorced	4 (2.8)
Separated	2 (1.4)
Religion	
Catholic	32 (22.5)
Protestant	104 (73.2)
Muslim	6 (4.2)
Education	
No formal education	7 (4.9)
Primary	55 (38.7)
Secondary	67 (47.2)
Tertiary	13 (9.2)
Medical insurance	
Yes	73 (51.4)
No	69 (48.6)
Type of insurance	
NHIF	73 (100.0)
Smoking	
No	142 (100)
Alcohol	
No	142 (100.0)

As illustrated in Table 1, the study population was relatively young with a mean age of 49.4 years. The male to female ratio was 1:46. Ninety - six (67.6%) of the patients were married. One hundred and thirty six (95%) participants were of Christian faith and only seven (4.9%) had no formal education. Seventy three patients (51.4%) had medical insurance cover from NHIF. None of the patients reported current use of alcohol or cigarettes.

Table 2: Knowledge on diagnosis, fertility counseling, and parity of study subjects

Variable	Frequency (%)
Diagnosis known	
Yes	142 (100)
Counseled on prognosis	
Yes	125 (88.0)
No	17 (12.0)
Family aware of diagnosis	
Yes	142 (100.0)
Received fertility counseling	
Yes	12 (8.4)
No	130 (91.6)
Parity	
Nulliparous	11 (7.7)
1 -4 children	97 (69.1)
More than 4 children	33 (23.2)

All of the patients were aware of their diagnosis and 88% had received prognosis counseling. All the patients had informed their families of their diagnosis. Twelve patients (8.4%) had been counseled on effects of treatment on fertility. Only eleven (7.7%) of our patients were nulliparous.

Table 3: Medical history and functional status of study subjects

Variable	Frequency (%)
Number of admissions due to this disease	
0	7 (4.9)
1	108 (76.1)
2	20 (14.1)
3	2 (1.4)
4	2 (1.4)
6	1 (0.7)
7	1 (0.7)
10	1 (0.7)
Blood transfusion	
Yes	11 (7.7)
No	131 (92.3)
ECOG score	
0	21 (14.8)
1	102 (71.8)
2	19 (13.4)

Regarding medical history, one hundred and eight (76.1%) of our participants had only one breast cancer related hospital admission. Eleven (7.7%) participants reported having a blood transfusion since diagnosis of breast cancer.

The general functional status of our patients as assessed by ECOG score was good with 71% of the population having a score of 1(fully ambulatory and able to carry out light work, but strenuous activity limited. (See Appendix 1).

Table 4: Tissue diagnosis and treatment modalities of study subjects

Variable	Frequency (%)
Tissue diagnosis	
Ductal cancer	120(84.5%)
Lobular	18(12.7)
Tubular	2(1.4)
Metaplastic	1(0.7)
Comedotype	1(0.7)
Surgery (ever)	
Yes	134 (94.4)
No	8 (5.6)
Chemotherapy (ever)	
Yes	119 (83.8)
No	24 (16.2)
Radiotherapy (ever)	
Yes	70 (49.3)
No	72 (50.7)
Hormonal therapy (ever)	
Yes	32 (22.5)
No	110 (77.5)
Targeted therapy (ever)	
No	142 (100)
Treatment combinations	**Frequency (%)**
Surgery and chemotherapy	38 (26.8)
Surgery, chemotherapy and radiotherapy	40 (28.2)
Surgery, chemotherapy, radiotherapy and tamoxifen	26 (18.3)
Chemotherapy and radiotherapy	2 (1.4)
Surgery alone	27 (19.0)
Chemotherapy alone	9 (6.3)

In this study population, one hundred and twenty (84.5%) of the participants had a histological diagnosis of ductal carcinoma. Other histological types seen were lobular(18%), tubular(1.4%), metaplastic(0.7%) and comedotype(0.7%).

Concerning exposure to different treatment modalities, 134(94.4%) patients had undergone surgery, 119(83.3%) had past or current exposure to chemotherapy, 70(49.3%) had past or current exposure to radiotherapy and 32(22.5%) had taken tamoxifen.

In terms of ongoing treatment modalities at the time of interview, participants were at different stages of therapy sequence. Fifty four (38%) patients were undergoing chemotherapy at the time of contact, with 25(17.6%) in the first half (3 cycles) of treatment and 29(20.4%) in the last half (3 cycles) of treatment. Twenty (14.1%) were post - surgery and awaiting chemotherapy. Thirty nine (27.5%) were undergoing radiotherapy. This is illustrated in figure 1 below.

Figure 1: Ongoing Treatment Modality of Study Subjects
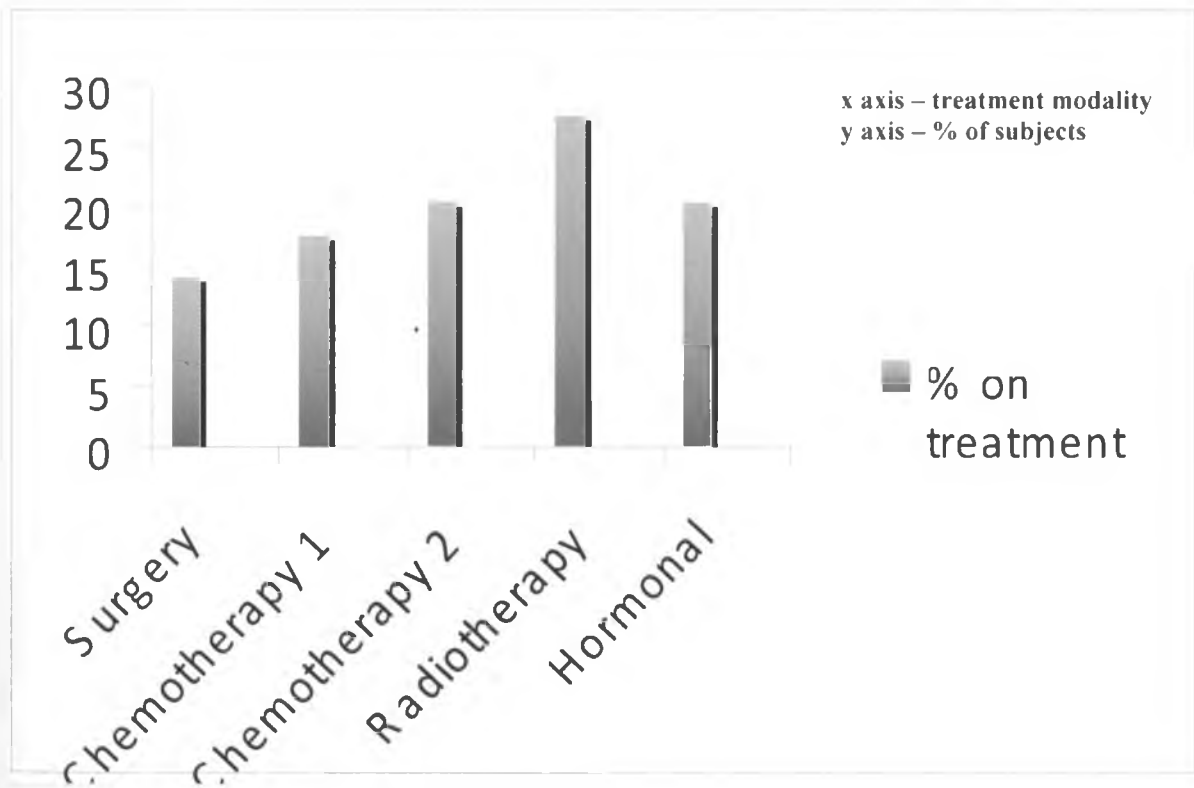
9.11 **Stage at Diagnosis**

Regarding the stage of disease at diagnosis, none of the patients had stage I disease. The proportion of patients who had presented in late stage disease were 53.5%, where 45.8% had presented in stage III disease, and 7.7% had presented in stage IV disease. Thirty three percent of the patients had presented in stage II disease. There was no documentation of stage of disease at diagnosis for 13.4% of the participants.

9.2 QUALITY OF LIFE SCORES

We then went ahead to establish the quality of life of our patients using the EORTC QLQ-C30/BR23 questionnaire.

The interpretation of the quality of life scores was based on the review by Koller et al[65] which recommended that a quality of life score of 50 points can be used to indicate clinically significant impairment in the EORTC questionnaire. For purposes of interpretation, our analysis was based on this, and depending on the parameter, the score 50 was used as the point of reference between better and worse quality of life.

Figure 2: Global Health Status/QoL

Mean = 65.48
SD = 19.885
Median = 66.7
IQR = 50 – 83.3
Min. = 16.7
Max. = 100
n = 142
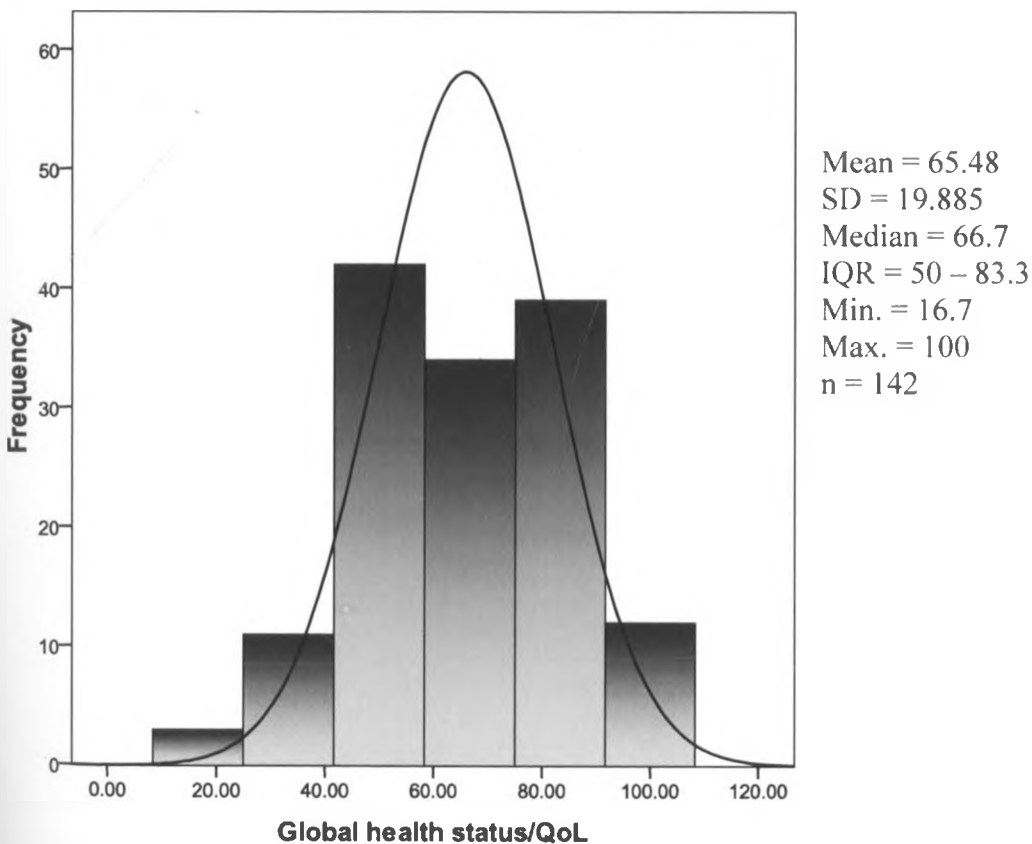
Global quality of life/health status scores were normally distributed as illustrated in figure 2 above, with a range from 0 – 100. Higher scores correspond to better quality of life, with 50 being the cutoff for good and poor quality of life. The mean global health status/QoL score in this study population was 65.5, with a median of 66.7 and interquartile range of 50 – 83.3.

Table 5: Breakdown of global health status/QoL scores

Global health status/QOL	Frequency (%)	
<=25	3 (2.1)	Good quality of life
26-50	53 (37.3)	
51-75	35 (24.6)	Poor quality of life
>75	51 (35.9)	

When Global quality of life/health status scores were categorized as shown in table 5 above, 3(2.1%) patients scored less than 25 thus having very poor quality of life, while 60.5% of patients scored above 50, which is good quality of life.

Table 6: Functional scales scores

Scale	Physical	Role	Emotional	Cognitive	Social	Body Image	Future Perspective	Sexual Function	Sexual Enjoyment
Mean	84.5	79.5	86.4	83.6	89	77.1	66.9	19.4	47.7
Median	86.7	100	91.7	100	100	83.3	66.7	1	33.3
% scoring <25	0	4.9	1.4	2.1	2.1	5.6	8.5	66.9	17.6
% scoring >75	78.2	65.5	76.1	73.9	78.9	54.2	50	3.5	15.7
% Scoring 25-74%	21.8	29.6	22.5	23	19	40.2	41.5	29.6	33.3

In the functional scales illustrated in table 6 above (measuring functional status of the patient in terms of physical, emotional, cognitive, social and role function, as well as body image, future perspective or optimism and sexual function), a higher score means a better functioning or better quality of life. The possible range of scores is $0 - 100$, and a score of more than 50 corresponds to good functional status, while a score of less than 50 corresponds to poor functional status.

In general for the functional scale scores, the patients had good physical function, emotional function, cognitive function, role function, social function and body image as mean scores in these categories were generally higher than 75.

Sexual functioning (libido and frequency of sexual contact) and sexual enjoyment were low with mean scores of 19.4 and 47.7 respectively.

9.23 Symptom scales (a parameter of quality of life)

The symptom scales are a measure of symptoms associated with breast cancer, as well as side effects of treatment. In the questionnaire used, financial difficulty was categorized as a symptom scale. Unlike the functional scales, in symptoms scales, a higher score corresponds to a worse or poorer quality of life. The possible range of scores is 0 – 100, and a score of more than 50 corresponds to poor quality of life (because of more symptoms and more financial difficulty), while a score of less than 50 corresponds to better quality of life (less symptoms and less financial difficulty).

The most commonly occurring symptoms were upset by hair loss (mean symptom scale score 23.1), fatigue (mean symptom scale score 22.1), pain (mean symptom scale score 19.4), systemic therapy side effects (mean symptom scale score 15.9), arm symptoms (mean symptom scale score 16.9), and breast symptoms (mean symptom scale score 16.9). The mean symptom scale scores for the other symptoms were 3.6 for nausea and vomiting, 4.7 for dyspnoea, 9.5 for insomnia, 3.3 for constipation, and 1.4 for diarrhea.

Table 7: Breakdown for financial difficulty

Score	Frequency (%)	
< 25	12 (8.5)	Less financial difficulty
26 – 50	25 (17.6)	
51 – 75	34 (23.9)	Greater financial difficulty
> 75	71 (50%)	

The mean score for financial difficulty was 71.8, which was high and corresponded to greater financial difficulty. When this was further categorized (as shown in table 7 above), 50% of the participants had scores of more than 75, indicating that many of the patients had significant financial difficulty.

9.3 ASSOCIATIONS BETWEEN VARIABLES

Bivariate analysis was then performed to explore associations between scores for quality of life/quality of life parameters and sociodemographic variables, stage at diagnosis and treatment modalities.

The global health status/quality of life score is an overall assessment of the quality of life of the patient. This score was associated with sociodemographic variables, ongoing treatment modalities, and breast cancer stage of disease; the associations are illustrated in tables 8 and 9 below:

Table 8: Associations between socio-demographic factors (age, marital status and education) and global health status/QoL

Variable	Global health status/QOL		OR (95% CI)	P value
	>=50 (better QoL)	<50 (worse QoL)		
Age, mean (SD)	49.3 (10.4)	49.4 (8.2)	-	0.996
Marital status				
Married	84 (66.1%)	11 (78.6%)	1.9 (0.5-7.1)	0.549
Unmarried	43 (33.9%)	3 (21.4%)	1.0	
Education				
None	5 (3.9%)	2 (14.3%)	1.0	
Primary	50 (39.4%)	4 (28.6%)	5.0 (0.7-34.5)	0.102
Secondary	59 (46.5%)	8 (57.1%)	2.9 (0.5-17.8)	0.238
Tertiary	13 (10.2%)	0 (0.0%)	-	-

In table 8 above, married participants were 1.9 times more likely to have better global quality of life/health status (with a score of >/= 50) than unmarried participants. This did not reach stastical significance (p-value 0.549). Participants with primary level education were 5 times more likely to have better global quality of life/health status than those with no education, while those with secondary level education were 2.9 times more likely to have better scores for global quality of life/health status than participants without

30

education.(p-value 0.102 and p-value 0.238 respectively). Though clinically important, these relationships did not reach statistical significance.

Table 9: Association between breast cancer stage at diagnosis, ongoing treatment modality and global health status/QoL

Variable	Global health status/QOL		OR (95% CI)	P value
	>=50 (better QoL)	<50 (worse QoL)		
Stage at diagnosis				
Stage II	44 (34.6%)	2 (14.3%)	1.0	
Stage III	54 (42.5%)	11 (78.6%)	0.2 (0.0-1.1)	0.059
Stage IV	10 (7.9%)	1 (7.1%)	0.5 (0.0-5.5)	0.536
Treatment				
Surgery	19 (15.0%)	1 (7.1%)	1.0	
Tamoxifen	25 (19.7%)	3 (21.4%)	0.4 (0.0-4.6)	0.490
Radiotherapy	33 (26.0%)	6 (42.9%)	0.3 (0.0-2.6)	0.267
Chemotherapy 1st 3 doses	24 (18.9%)	1 (7.1%)	1.3 (0.1-21.5)	0.872
Chemotherapy last 3 doses	26 (20.5%)	3 (21.4%)	0.5 (0.0-4.7)	0.511

The association between global health status and stage of disease as well as ongoing treatment modality is illustrated in table 9 above. For stage of diagnosis, stage II disease was used as the comparator because it was the earliest stage at which any patient presented. For treatment modality, surgery was selected as the comparator because majority of the patients had undergone surgery (the few who had not were excluded from this analysis) and because it is a non-systemic form of treatment unlike all the others.

There was a trend towards patients with advancing stage of disease being less likely to have a good global quality of life/health status. Patients in breast cancer stage III disease were less likely to have good global quality of life scores than those in stage II disease, although statistical significance was not reached. (OR 0.2; p-value 0.059).

31

Associations between the individual parameters of quality of life (functional status scales and symptom scales) and sociodemographic variables, ongoing treatment modalities and breast cancer stage of disease are illustrated and explained in tables 10 to 16.

Table 10: Association between Physical functioning scores and Sociodemographic variables (age, marital status, and education)

Variable	Physical functioning scores		OR (95% CI)	P value
	>=50 (better)	<50 (worse)		
Age, mean (SD)	49.2 (10.2)	56.5 (8.4)		0.163
Marital status, n (%)				
Married	94 (68.1%)	2 (50.0%)	2.1(0.1-3.4)	0.595
Unmarried	44 (31.9%)	2 (50.0%)	1.0	
Education, n (%)				
None	6 (4.3%)	1 (25.0%)	1.0	
Primary	54 (39.1%)	1 (25.0%)	9.0 (0.5-163.1)	0.137
Secondary	65 (47.1%)	2 (50.0%)	5.4 (0.4-68.8)	0.193
Tertiary	13 (9.4%)	0 (0.0%)		0.999

The association between physical function and sociodemographic variables (age, marital status and education) is illustrated in table 10 above.

For physical functioning, married participants were 2.1 times more likely to have better physical functioning scores than unmarried participants. Participants with primary level education were 9 times more likely to score better for physical function than participants without formal education. Participants with secondary level education were 5.4 times more likely to have better physical function scores than those without formal education. These however did not reach statistical significance.

Table 11: Association between Role functioning scores and sociodemographic variables, breast cancer stage at diagnosis and ongoing treatment modality

Variable	Role functioning scores		OR (95% CI)	P value
	>=50 (better)	<50 (worse)		
Age, mean (SD)	49.0 (9.5)	52.2 (14.0)		0.206
Marital status, n (%)				
Married	90 (73.2%)	6 (31.6%)	5.9 (2.1-16.8)	0.001
Unmarried	33 (26.8%)	13 (68.4%)	1.0	
Education, n (%)				
None	2 (1.6%)	5 (26.3%)	1.0	
Primary	47 (38.2%)	8 (42.1%)	14.7 (2.4-89.1)	0.003
Secondary	61 (49.6%)	6 (31.6%)	25.4 (4.1-160.3)	0.001
Tertiary	13 (10.6%)	0 (0.0%)	-	0.998
Stage at diagnosis, n (%)				
Stage II	41 (33.3%)	6 (31.6%)	1.0	
Stage III	59 (48.0%)	6 (31.6%)	1.4 (0.4-4.8)	0.552
Stage IV	8 (6.5%)	3 (15.8%)	0.4 (0.1-1.9)	0.243
Treatment, n (%)				
Surgery	19 (15.4%)	1 (5.3%)	1.0	
Tamoxifen	28 (22.8%)	1 (5.3%)	1.5 (0.1-25.0)	0.788
Radiotherapy	35 (28.5%)	4 (21.1%)	0.5 (0.1-4.4)	0.502
Chemotherapy 1st 3 doses	15 (12.2%)	10 (52.6%)	0.1 (0.0-0.7)	0.021
Chemotherapy last 3 doses	26 (21.1%)	3 (15.8%)	0.5 (0.0-4.7)	0.511

The association between role function scores and sociodemographic variables (age, marital status, education), as well as stage at diagnosis and ongoing treatment modality has been illustrated in table 11 above. For stage of diagnosis, stage II disease was used as the comparator because it was the earliest stage at which any patient presented. For treatment modality, surgery was selected as the comparator because majority of the patients had undergone surgery (the few who had not were excluded from this analysis) and because it is a non-systemic form of treatment unlike all the others.

In this population, being married was significantly associated with having better role function scores than being single ((OR 5.9; p-value 0.001). Participants with primary

level education were more likely to have better role function scores than those without formal education (OR 14.7 p-value 0.003). The participants who had reached secondary level education were 25.4 times more likely to have better role function scores than those without formal education (p–value 0.001). Patients who were receiving any of their first 3 courses of chemotherapy had lower role function scores, and this was found to be statistically significant (p=0.021).

Though not statistically significant, patients with stage IV disease were less likely to have better scores for role function.

Table 12: Association between Emotional functioning scores and sociodemographic variables, breast cancer stage at diagnosis

Variable	Emotional functioning scores		OR (95% CI)	P value
	>=50 (better)	<50 (worse)		
Age, mean (SD)	49.3 (10.0)	52.7 (15.5)		0.388
Marital status, n (%)				
Married	93 (68.9%)	3 (42.9%)	2.95(0.1-1.6)	0.214
Unmarried	42 (31.1%)	4 (57.1%)	1.0	
Stage at diagnosis, n (%)				
Stage II	46 (34.1%)	1 (14.3%)	1.0	
Stage III	60 (44.4%)	5 (71.4%)	0.3 (0.0-2.3)	0.227
Stage IV	11 (8.1%)	0 (0.0%)	-	0.999

The association between emotional function and sociodemograhic variables (age, marriage) and breast cancer stage at diagnosis is illustrated in table 12 above.

For stage of diagnosis, stage II disease was used as the comparator because it was the earliest stage at which any patient presented.

Regarding scores for emotional functioning, in this study population, married participants were 2.95 times more likely to have better emotional functioning scores than unmarried participants. This however did not reach statistical significance.

Table 13: Association between Cognitive functioning and sociodemographic variables

Variable	Cognitive functioning scores		OR (95% CI)	P value
	>=50 (better)	<50 (worse)		
Age, mean (SD)	50.0 (10.0)	55.0 (11.5)		0.061
Marital status, n (%)				
Married	93 (71.0%)	3 (27.3%)	6.5(1.6-2.59)	0.005
Unmarried	38 (29.0%)	8 (72.7%)	1.0	
Education, n (%)				
None	4 (3.1%)	3 (27.3%)	1.0	
Primary	51 (38.9%)	4 (36.4%)	9.6 (1.6-58.4)	0.014
Secondary	64 (48.9%)	3 (27.3%)	16.0 (2.4-106.2)	0.004
Tertiary	12 (9.2%)	1 (9.1%0	9.0 (0.7-113.0)	0.089

The association between cognitive function and sociodemographic factors is illustrated in table 13 above.

Regarding scores for cognitive function, in our study population, being married was associated with better cognitive function scores than being unmarried (OR 6.5; p=0.005). Participants with primary and secondary levels of education also had significantly better scores in cognitive function that the participants who had not received any formal education. (OR 9.6; p=0.014 and OR 16; p=0.004 respectively).

Table 14: Association between Social functioning scores and sociodemographic variables, breast cancer stage at diagnosis and ongoing treatment modality

Variable	Social functioning scores		OR (95% CI)	P value
	>=50 (better)	<50 (worse)		
Age, mean (SD)	49.4 (10.3)	51.0 (10.2)		0.759
Marital status, n (%)				
Married	94 (68.1%)	2 (50.0%)	2.1 (0.3-15.7)	0.595
Unmarried	44 (31.9%)	2 (50.0%)	1.0	
Education, n (%)				
None	6 (4.3%)	1 (25.0%)	1.0	
Primary	55 (39.9%)	0 (0.0%)	-	0.997
Secondary	65 (47.1%)	2 (50.0%)	5.4 (0.4-68.8)	0.193
Tertiary	12 (8.7%)	1 (25.0%)	2.0 (0.1-37.8)	0.644
Stage at diagnosis, n (%)				
Stage II	47 (34.1%)	0 (0.0%)		
Stage III	63 (45.7%)	2 (50.0%)	-	
Stage IV	9 (6.5%)	2 (50.0%)		0.033
Treatment, n (%)				
Surgery	19 (13.8%)	1 (25.0%)	1.0	
Tamoxifen	28 (20.3%)	1 (25.0%)	1.5 (0.1-25.0)	0.788
Radiotherapy	38 (27.5%)	1 (25.0%)	2.0 (0.1-33.8)	0.631
Chemotherapy 1st 3 doses	24 (17.4%)	1 (25.0%)	1.3 (0.1-21.5)	0.872
Chemotherapy last 3 doses	29 (21.0%)	0 (0.0%)	-	0.998

The association between social function and sociodemographic factors (age, marital status and education), breast cancer stage at diagnosis and ongoing treatment modality are illustrated in table 14 above.

For stage of diagnosis, stage II disease was used as the comparator because it was the earliest stage at which any patient presented. For treatment modality, surgery was selected as the comparator because majority of the patients undergone surgery (the few

who had not were excluded from this analysis) and because it is a non-systemic form of treatment unlike all the others.

Regarding social function, patients with stage 4 at diagnosis had lower social function scores than patients with lower stage of disease at diagnosis, and this reached statistical significance.(p=0.003).

Table 15: Association between Pain scores and sociodemographic variables, breast cancer stage of disease and ongoing treatment modalities

Variable	Pain scores		OR (95% CI)	P value
	>=50 (worse)	<50 (better)		
Age, mean (SD)	50.9 (11.3)	49.2 (10.1)	-	0.480
Marital status, n (%)				
Married	11 (50.0%)	85 (70.8%)	0.4 (0.2-1.0)	
Unmarrried	11 (50.0%)	35 (29.2%)	1.0	0.081
Education, n (%)				
None	1 (4.5%)	6 (5.0%)	1.0	
Primary	13 (59.1%)	42 (35.0%)	1.9 (0.2-16.9)	0.582
Secondary	7 (31.8%)	60 (50.0%)	0.7 (0.1-6.7)	0.757
Tertiary	1 (4.5%)	12 (10.0%)	0.5 (0.0-9.5)	0.644
Stage at diagnosis, n (%)				
Stage II	4 (18.2%)	43 (35.8%)	1.0	
Stage III	12 (54.5%)	53 (44.2%)	2.4 (0.7-8.1)	0.147
Stage IV	4 (18.2%)	7 (5.8%)	6.1 (1.2-30.4)	0.026
Treatment, n (%)				
Surgery	3 (13.6%)	17 (14.2%)	1.0	
Tamoxifen	4 (18.2%)	25 (20.8%)	0.9 (0.2-4.6)	0.906
Radiotherapy	7 (31.8%)	32 (26.7%)	1.2 (0.3-5.4)	0.775
Chemotherapy 1st 3 doses	6 (27.3%)	19 (15.8%)	1.8 (0.4-8.3)	0.457
Chemotherapy last 3 doses	2 (9.1%)	27 (22.5%)	0.4 (0.1-2.8)	0.368

The association between pain scores and sociodemographic variables (age, marital staus, education), breast cancer stage at diagnosis, and ongoing treatment modality is illustrated in table 15 above. For stage of diagnosis, stage II disease was used as the comparator because it was the earliest stage at which any patient presented. For treatment modality, surgery was selected as the comparator because majority of the patients had undergone surgery (the few who had not were excluded from this analysis) and because it is a non-

systemic form of treatment unlike all the others. Regarding pain scores, higher scores (more than 50) correspond to perception of more pain by the respondent.

In this population, participants with stage 4 disease were significantly more likely to have higher pain scores than participants with stage II disease. (OR 6.1; p=0.026).

There was a trend towards married participants being less likely to have higher pain scores than unmarried participants. (p=0.081).

Table 16: Association between Financial difficulties and sociodemographic variables, breast cancer stage of disease and ongoing treatment modality

Variable	Financial difficulty		OR (95% CI)	P value
	>=50 (worse)	<50 (better)		
Age, mean (SD)	49.7 (10.1)	48. 8 (10.7)		0.652
Marital status, n (%)				
Married	75 (71.4%)	21 (56.8%)	1.9 (0.9-4.1)	0.101
Unmarried	30 (28.6%)	16 (43.2%)	1.0	
Education, n (%)				
None	5 (4.8%)	2 (5.4%)	1.0	
Primary	41 (39.0%)	14 (37.8%)	1.2 (0.2-6.7)	0.859
Secondary	51 (48.6%)	16 (43.2%)	1.3 (0.2-7.2)	0.784
Tertiary	8 (7.6%)	5 (13.5%)	0.6 (0.1-4.7)	0.659
Medical insurance, n (%)				
Yes	52 (49.5%)	21 (56.8%)	0.7 (0.4-1.6)	0.449
No	53 (50.5%)	16 (43.2%)	1.0	
Stage at diagnosis, n (%)				
Stage II	29 (27.6%)	18 (48.6%)	1.0	
Stage III	54 (51.4%)	11 (29.7%)	3.0 (1.3-7.3)	0.013
Stage IV	10 (9.5%)	1 (2.7%)	6.2 (0.7-52.7)	0.094
Treatment, n (%)				
Surgery	13 (12.4%)	7 (18.9%)	1.0	
Tamoxifen	16 (15.2%)	13 (35.1%)	0.7 (0.2-2.1)	0.492
Radiotherapy	33 (31.4%)	6 (16.2%)	3.0 (0.8-10.5)	0.093
Chemotherapy 1st 3 doses	19 (18.1%)	6 (16.2%)	1.7 (0.5-6.2)	0.421
Chemotherapy last 3 doses	24 (22.9%)	5 (13.5%)	2.6 (0.7-9.8)	0.162

Financial difficulty was associated with sociodemographic variables(age, marital status, education, medical insurance status), breast cancer stage of disease and ongoing treatment modality as shown in table 16.

For stage of diagnosis, stage II disease was used as the comparator because it was the earliest stage at which any patient presented. For treatment modality, surgery was selected as the comparator because majority of the patients undergone surgery (the few who had not were excluded from this analysis) and because it is a non-systemic form of treatment unlike all the others.

Higher scores in this category (more than 50) correspond to greater financial difficulty. In this population, participants in stage 3 disease at diagnosis were more likely to score higher for financial difficulties than patients in stage 2 disease at diagnosis (OR 3; $p=0.013$). There was a trend towards participants undergoing radiotherapy being 3 times more likely to experience greater financial difficulty ($p=0.09$). No significant association was found between financial difficulty and age, marital status, level of education, and presence or absence of medical insurance.

10.0 DISCUSSION

In this study, we set out to establish the health related quality of life of breast cancer patients receiving treatment at the outpatient clinics of Kenyatta National Hospital, and to find out how this is influenced by patients' sociodemographic characteristics, breast cancer stage at diagnosis and ongoing treatment modalities.

The study population was young, predominantly female and at various stages of breast cancer treatment. Most of the population were married, had some level of education and majority had presented to hospital in late stage (stage III and stage IV) disease. These characteristics of the sample population were similar to the findings of Maranga et al who studied the reasons for late presentation on the same breast cancer population in Kenyatta National Hospital[39].

The interpretation of the quality of life scores was based on the review by Koller et al[65] which recommended that a quality of life score of 50 points and below can be used to indicate clinically significant impairment in the EORTC questionnaire. For purposes of interpretation, our analysis was based on this, and depending on the parameter, the score 50 was used as the point of reference between better and worse quality of life.

The average overall quality of life scores of our patients was 65.5 with a standard deviation of 19.9. Only 3 patients had scores of less than 25. By international standards, these are good scores. Mean international values given by breast cancer patients using the EORTC tool are 61.8 with a standard deviation of 24.6. Hoyer et al[68] in Sweden found a score of 65 while Amdt et al[67] in Germany found a score of 65.3. These European studies were carried out on patients with similar characteristics to our study; patients at different stages of disease and undergoing different modalities of treatment. However, the age of our population was younger. In contrast, Alawadi et al[69] reported a mean score of 45.3 in Kuwaiti patients, however most of this population were undergoing chemotherapy, unlike our mixed treatment population.

Being a developing country with less resources for health care and with our patients presenting in later stage disease, one would have expected lower quality of life scores from our patients; perhaps factors such as social support contributed to our population having comparable scores. In the domain of social functioning, the patients in our study

had a mean score of 89 while Hoyer et al[68] reported a mean score of 75 in the same domain and Alawadi et al[69] reported a mean score of 61.2. Our study participants reported good physical, social, cognitive and emotional function. These scores are better than those reported in breast cancer patients in other studies[65-71]. Our patients may have better quality social support than counterparts in Western countries as supported by other studies[51]. However, one would have expected similar scores in a study carried out on Nigerian breast cancer patients by Jayesimi et al[66], who should have similar social structure to Kenya. They had lower scores on all counts of functional status, particularly social function where a score of 40.9 was given. Perhaps the size of that study (n=35) did not give a true reflection of the rest of their breast cancer patients.

In general, symptoms and side effects scores were low, with most patients reporting few side effects which were tolerable. Part of the reason may be that most patients undergoing chemotherapy and radiotherapy were interviewed before their next session, and not immediately after. Most patients suffer side effects of treatment for a few hours to days after but recover before their next treatment schedule. In a study of Nigerian breast cancer patients undergoing adjuvant therapy, Ketiku et al[70] also reported that side effects due to treatment were low. A different questionnaire was used though, but the adjuvant drug regimen was similar to that used in our study.

In our study, fatigue, pain, appetite loss, arm and breast symptoms were the main complaints. Most patients were not bothered by hair loss, probably because it is temporary, and in our set up, it is culturally acceptable for women to keep short hair. The patients studied by Alawadi et al[69] in Kuwait were more bothered by hair loss (mean scores 44.8) and this could be due to socio-cultural differences. Fatigue has been found to be the main complaint from breast cancer patients in several studies and ours is no exception. In a study by Amdt et al[49], fatigue was found to be a major predictor of quality of life.

Financial difficulties were a major complaint in our study with scores of 71.4. This is not surprising in a population attending a public hospital in a third world country with a developing economy (per capita income $1600) where health care is not free. In contrast, patients in Sweden (per capita income $38,500) where health care is largely covered by

the government, scored 16.4 on the same, while patients in Kuwait (per capita income $57,400) scored 31.2. In our country, there has been preferential distribution of health care resources other diseases such as HIV, compared to cancer.

Sexual functioning was low (interest and frequency of sexual contact), while those who had any sexual contact reported average enjoyment at a score of 47. The reasons for this include effects of the disease and its treatments on psychological and physical aspects of sexuality. A few patients pointed out that it was their partners who decided to 'give them space' in view of their illness. The issue of sexuality is greatly influenced by how women and their partners view mastectomy. The breast is an organ of sexuality and fertility and loss of one breast may be viewed as a loss of these. Polygamy (whether official or unofficial) is common in African societies, and male partners may seek sexual satisfaction elsewhere, contributing to this low score. A study done in Nigeria by Odigie et al[71] reported that even months to years after mastectomy, there was a decrease in conjugal relations reported by married patients, and an increased rate of divorce. Another possible reason for this low score could be response bias, in view of the sensitivity of this topic and the privacy it attracts.

Married participants were found to have better global health status/QoL, better role function and better cognitive function. They were also more likely to have lower pain scores. Marriage is really a form of social support, and good social support has a positive influence on quality of life. In addition, married people may receive financial help from their partners, thus contributing to their better quality of life. Studies done on breast cancer, and indeed other cancer patients have shown that living alone is associated with poor quality of life scores[72,73].

We also found that having an education also resulted in better quality of life, better role and better cognitive function scores. Several studies have associated lower level of education with poorer health related quality of life scores[73-75]. This may be explained by the fact that those who are educated may have more access to salaried employment, more access to economic resources and consequently an increased sense of control.

Amongst the different treatment modalities, in our study, those undergoing chemotherapy had worse role function. Breast cancer patients studied by Alawadi et al[69] had relatively

poor quality of life scores when compared with our study. The main difference in Alawadi's study was the fact that majority of his patients were undergoing chemotherapy. Systemic chemotherapy is associated with significant side effects and this may explain why out of all other treatment modalities in our study, associations with lower quality of life were found with it.

Patients receiving radiotherapy had more financial difficulty. The possible explanation is that during radiotherapy, patients have to visit the hospital daily for six weeks, and this involves transport costs, payments for treatments, accommodation costs for those from upcountry, and clinic visits.

In our study population, participants with higher stage of disease were more likely to have worse quality of life, poorer functional scale scores, more symptoms and more financial difficulty. It is not surprising that higher stage of disease would cause more symptoms because of spread of disease. As well, these patients are more likely to have frequent hospital admissions, have frequent clinic visits, and spend more money on medication such as analgesics and other supportive treatments, hence the increased financial difficulty. Patients with advanced stage of disease are also likely to have stopped working for a living, and this would add to their financial stress.

Spirituality and religion are important aspects of quality of life especially in our society. However, the tool that we used to assess quality of life omitted this aspect.

10.1   Strengths

This is the first study on quality of life of breast cancer patients in the haemato-oncology and cancer treatment centres of Kenyatta National Hospital. The sample population included patients at various stages of treatment and various stages of disease, giving a broad picture of the quality of life issues of these patients and forming a basis for further evaluation of quality of life issues in this population.

10.2   Limitations

Some of the questions in the interviews were of a personal nature and therefore response bias is a possible limitation in the form of under-reporting.

Participants were required to recall events as far back as a month prior to the interview, and therefore, recall bias is also a possible limitation

10.3   Conclusion

The findings of this study show that the overall quality of life of breast cancer patients in Kenyatta National Hospital is good, and similar to that of breast cancer patients in the West, despite the fact that our patients present in late stage disease and despite the more limited resources for healthcare in support in our set-up. Among the individual parameters of quality of life measured, scores for social support were high and this may be the one of the contributory factors. There was however significant financial difficulty reported by our participants.

10.4   Recommendations

Support should be provided to single patients, as well as those with advanced stage of disease in terms of counseling and peer groups in order to give them the advantage of social support.

Health advocates should demand for more financial support for cancer patients.

Interventional studies utilizing finances and social support should be carried out in order to document improvement in quality of life once these are in place.

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APPENDIX 1: STUDY PROFORMA

CLINIC: STUDY SERIAL NUMBER:

DATE:

SOCIAL DEMOGRAPHIC AND BIO DATA (tick or fill in as appropriate)

Age				
Gender	Male		Female LMP	
Marital Status	Single	Married		Widowed
	Divorced	Other		
Usual Residence				
Religion	Catholic	Protestant	Muslim	Other [specify]
Education	1° 2°	3°	None	
Medical insurance (up to date)	Yes In - patient Out patient	No		
Occupation (current)				
Smoking	Yes	No		

Alcohol	Yes	No
Do you know your diagnosis?	Yes	No
Have you been counseled on prognosis?	Yes	No
Family aware of diagnosis?	Yes	No
Family supportive?	Yes	No

FERTILITY (tick or fill in as appropriate)

Number of children	None	1-4	More than 4
	Received fertility counseling: Yes No		

MEDICAL HISTORY (tick or fill in as appropriate)

Number of Admissions due to this disease		
History of blood transfusion	Yes How many?	No
Co – morbidities (list)	• •	

	•
	•
	•
Drugs - long term use(apart from cancer drugs)	

CLINICAL DATA (fill in as appropriate)

General physical examination	General comment					
	BP	Wt	Pale	Jaundice	Oedema	LNS
ECOG score	0	1	2	3	4	

54

CANCER INFORMATION (tick or fill in as appropriate)

Tissue diagnosis			
Date of diagnosis			
Where diagnosis was made(name of hosp)			
Stage at diagnosis			
Intention of treatment	Cure	Palliative	
Surgery	Yes When?(year)		No
Chemotherapy	Yes Current regimen (name drugs) Frequency Past regimen if any(name drugs)		No
Radiotherapy	Yes When(year,month)?		No

Hormonal therapy	Yes (specify)	No
Targeted therapy	Yes (specify)	No

ECOG SCORE

0 – fully active, no performance restrictions

1 – Strenuous physical activity restricted; fully ambulatory and able to carry out light work

2 – capable of all self care but unable to carry out any work activities. Up and about more 50% of waking hours

3 - capable of only limited self care; confined to bed or chair more than 50% waking hours.

4 – completely disabled; cannot carry out any self care; totally confined to bed or chair.

APPENDIX 2: TNM STAGING SYSTEM FOR BREAST CANCER

Primary tumour (T)

TX - Primary tumor cannot be assessed

T0 - No evidence of tumor

Tis - Carcinoma in situ

Tis - (DCIS) Ductal carcinoma in situ

Tis - (LCIS) Lobular carcinoma in situ

Tis - (Paget) Paget disease of the nipple with no tumor*

T1 - Tumor ≤ 2 cm

T1 -mic ≤ 0.1 cm

T1a - > 0.1 cm – 0.5 cm

T1b - > 0.5 cm – 1 cm

T1c - > 1 cm – 2 cm

T2 - Tumor > 2 cm – 5 cm

T3 - Tumor > 5 cm

T4 - Tumor of any size with direct extension to (a) chest wall or (b) skin, only as described below

T4a - Extension to chest wall, not including pectoralis muscle

T4b - Edema (including peau d'orange) or ulceration of the skin of the breast, or satellite skin nodules confined to the same breast

T4c - Both T4a and T4b

T4d - Inflammatory carcinoma

Regional lymph nodes (N) : Clinical classification

NX - Regional lymph nodes cannot be assessed (e.g., previously removed)

N0 - No regional lymph node metastasis

N1 - Metastasis in movable ipsilateral axillary lymph node or nodes

N2 - Metastasis in ipsilateral axillary lymph nodes or in clinically apparent† ipsilateral internal mammary nodes in the absence of clinically evident lymph node metastasis

N2a - Metastasis in ipsilateral axillary lymph nodes fixed to one another (matted) or to other structures

N2b - Metastasis only in clinically apparent† ipsilateral internal mammary nodes and in the absence of clinically evident axillary lymph node metastasis

N3 - Metastasis in ipsilateral infraclavicular lymph node or nodes or in clinically apparent† ipsilateral internal mammary lymph node or nodes and in the presence of clinically evident axillary lymph node metastasis; or metastasis in ipsilateral supraclavicular lymph node or nodes with or without axillary or internal mammary lymph node involvement

N3a - Metastasis in ipsilateral infraclavicular lymph node or nodes and axillary lymph node or nodes

N3b - Metastasis in ipsilateral internal mammary lymph node or nodes and axillary lymph node or nodes

N3c - Metastasis in ipsilateral supraclavicular lymph node or nodes

Regional lymph nodes : Pathological classification (pN)

pNX - Regional lymph nodes cannot be assessed (e.g., previously removed)

pN0 - No regional lymph node metastasis histologically, no additional examination for isolated tumor cells§

pN0(i-) - No regional lymph node metastasis histologically, negative IHC

pN0(i+) - No regional lymph node metastasis histologically, positive IHC, no IHC cluster > 0.2 mm

pN0(mol-) - No regional lymph node metastasis histologically, negative molecular findings (RT-PCR)

pN0(mol+) - No regional lymph node metastasis histologically, positive molecular findings (RT-PCR)

pN1mi - Micrometastases (> 0.2 mm, none > 2.0 mm)

pN1 - Metastasis in one to three axillary lymph nodes and/or in internal mammary nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent‖¶

pN1a - Metastasis in one to three axillary lymph nodes

pN1b - Metastasis in internal mammary nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent||

pN1c - Metastasis in one to three axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by sentinel

lymph node dissection but not clinically apparent ||¶

pN2 - Metastasis in four to nine lymph nodes or in clinically apparent† internal mammary lymph nodes in the absence of axillary lymph node metatasis

pN2a - Metastasis in four to nine axillary lymph nodes (at least one tumor deposit > 2.0 mm)

pN2b - Metastasis in clinically apparent† internal mammary lymph nodes in the absence of axillary lymph node metastasis

pN3 - Metastasis in 10 or more axillary lymph nodes, in infraclavicular lymph nodes, or in clinically apparent† ipsilateral internal mammary lymph

nodes in the presence of one or more positive axillary lymph nodes; or in more than three axillary lymph nodes with clinically negative microscopic

metastasis in internal mammary lymph nodes; or in ipsilateral lymph nodes

pN3a - Metastasis in 10 or more axillary lymph nodes (at least one tumor deposit > 2.0 mm), or metastasis to the infraclavicular lymph nodes

pN3b - Metastasis in clinically apparent† ipsilateral internal mammary lymph nodes in the presence of one or more positive axillary lymph nodes;

or in more than three axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph

node dissection but not clinically apparent||

pN3c - Metastasis in ipsilateral supraclavicular lymph nodes

Distant metastasis (M)

MX - Distant metastasis cannot be assessed

M0 - No distant metastases

M1 - Distant metastasis

IHC—immunohistochemistry RT-PCR —reverse transcriptase polymerase chain reaction ◄

*Paget disease associated with a tumor is classified according to the size of the tumor.

†Clinically apparent is defined as detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination.

‡Classification is based on axillary lymph node dissection with or without sentinel lymph node dissection. Classification based solely on sentinel lymph node dissection without subsequent axillary lymph node dissection is designated as "sn," for sentinel node (e.g., pN0[i+][sn]).

§Isolated tumor cells are defined as single tumor cells or small cell clusters not greater than 0.2 mm, usually detected only by immunohistochemical or molecular methods but which may be verified by hematoxylin and eosin stains.

‖Not clinically apparent is defined as not detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination.

¶If associated with more than three positive axillary lymph nodes, the internal mammary nodes are classified as pN3b to reflect increased tumor burden

APPENDIX 3: TNM STAGE GROUPING FOR BREAST CANCER

	T	N	M
	T	N	M
Stage 0	Tis	N0	Mo
Stage I	T1	N0	Mo
Stage IIa	T0	N1	M0
	T1	N1	
	T2	N0	
Stage IIb	T2	N1	M0
	T3	N0	
Stage IIIa	T0	N2	M0
	T1	N2	
	T2	N2	
	T3	N1,2	
Stage IIIb	T4	Any N	M0
	Any T	N3	
Stage IIIc	Any T	N3	M0
Stage IV	Any T	Any N	M1

APPENDIX 4: ADJUVANT CHEMOTHERAPY REGIMENS

ACRONYM	DRUGS	DOSE	SCHEDULE
CMF	Cyclophosphamide Methotrexate Fluorouracil	100 mg/m2/day p.o. × 14 days 40 mg/m2 I.V. days 1 and 8 600 mg/m2 I.V. days 1 and 8	Repeated every 28 days for six cycles
CAF	Cyclophosphamide Doxorubicin Fluorouracil	100 mg/m2/day p.o. × 14 days 30 mg/m2 I.V. days 1 and 8 500 mg/m2 I.V. days 1 and 8	Repeated every 28 days for six cycles
FAC	Fluorouracil Doxorubicin Cyclophosphamide	500 mg/m2 I.V. days 1 and 8 50 mg/m2 I.V. day 1 500 mg/m2 I.V. day 1	Repeated every 21 days for six cycles
AC	Doxorubicin Cyclophosphamide	60 mg/m2 I.V. day 1 600 mg/m2 I.V. day 1	Repeated every 21 days for four cycles
AC – T	Doxorubicin Cyclophosphamide *Followed by* Paclitaxel	60 mg/m2 I.V. day 1 600 mg/m2 I.V. day 1 175 mg/m2 I.V. day 1	Repeated every 21 days for four cycles Repeated every 21 days for four cycles
DOSE – DENSE AC – T	Same as AC – T	Same as AC → T	Repeated every 14 days for four cycles with G-CSF suppor

AC – DOCETAXEL	Doxorubicin	60 mg/m2 I.V. day 1	Repeated every 21 days for four cycles
	Cyclophosphamide	600 mg/m2 I.V. day 1	
	Followed by		
	Docetaxel	100 mg/m2 I.V. day 1	Repeated every 21 days for four cycles
TAC	Docetaxel	75 mg/m2 I.V. day 1	Repeated every 21 days for six cycles
	Doxorubicin	50 mg/m2 I.V. day 1	
	Cyclophosphamide	500 mg/m2 I.V. day 1	
FEC	Fluorouracil	Various doses	Various schedules
	Epirubicin		
	Cyclophosphamide		

APPENDIX 5: PATIENT INFORMATION FORM

My name is Dr. Nakitare. I am a post – graduate student of Internal Medicine at the University of Nairobi. The purpose of this statement is to inform you about a research study that I am carrying out.

I am carrying out a research study on the quality of life of cancer patients attending Kenyatta National Hospital. The aim of the study is to find out how patients who have breast cancer are coping from their own perspective. Recommendations can then be made to the health care providers on interventions that can improve the quality of life of our patients.

Participation in this study is voluntary. Should you accept to participate, then the following is a summary of what the study involves:

1. Obtaining socio-demographic information such as age, gender and residence from the patient.
    NOTE : Your name and hospital identification number shall not be included in this information for your privacy.
2. Obtaining information about the treatment modalities that have been used.
3. A physical examination – similar to the examination that your primary doctor usually performs. It includes listening to your chest and palpating your abdomen. It will be performed by a qualified medical practitioner.
4. Administration of a questionnaire to assess aspects of quality of life.
5. This will require about half an hour of your time.

Please note that your identity shall not be recorded nor revealed to any other person(s).
All information will be treated as confidential.

Your primary health physician shall be informed of any findings relevant to your medical care.

A consent form shall be supplied for you to sign if you agree to participate.

If you do not agree to participate, there will be NO consequences. You medical care will continue as usual.

Even if you agree to participate, you are free to withdraw from the study at any time with NO consequences at all.

Thank you for taking time to read this information.

If you have any questions, please do not hesitate to ask.

Clarifications may also be addressed to any of the following :

Dr. Nakitare S.K.
P.O.Box 19676
Nairobi.
Telephone: 0724-165621

Prof. M.D. Joshi
Department of clinical medicine and therapeutics
University of Nairobi
P.O.Box 19676.
Nairobi.

Dr. G. Kiarie
Department of clinical medicine and therapeutics
University of Nairobi
P.O.Box 19676
Nairobi.

The Chairman of the Ethics and Research Committee
Kenyatta National Hospital
020-2726300/0722-829500/0733-606400 ext.44102

APPENDIX 6: CONSENT FORM

I...hereby consent to take part in this research study on the quality of life of breast cancer patients.

The nature of this study has been explained to me by Dr. Nakitare S.K/her assistant.

I have been assured that participation in this study is voluntary and will not negatively affect my medical care, and that any information obtained will be treated as confidential.

Signed/thumbprint..

On this day and date................................

Witness...

Date..

Investigator's Statement

I, the investigator, have provided an explanation on the purpose and implications of the above research study to the participant.

Signed......................................

On this day and date.............................