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BAHIR DAR UNIVERSITY

COLLEGE OF MEDICINE AND HEALTH SCIENCES

SCHOOL OF MEDICNE

DEPARTMENT OF GYNECOLOGY AND OBSTETRICS

Health Related Quality Of Life Among Gynecologic Cancer Patients At Government Hospitals In Bahirdar; Ethiopia

PRINCIPAL INVESTIGATOR: Walelign Kindie (GYNECOCLOGIC ONCOLOGY FELLOW)

A THESIS RESEARCH SUBMITTED TO DEPARTMENT Of GYNECOLOGY AND OBSTETRICS, SCHOOL OF MEDICNE, COLLEGE OF MEDICINE AND HEALTH SCIENCES IN PARTIAL FULFILLMENT OF THE REQUIRMENTS FOR SUBSPECIALITY CERTEFICATE IN GYNECOLOGIC ONCOLOGY

DEC, 2024

BAHIR DAR UNIVERSITY

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HEALTH RELATED QUALITY OF LIFE AMONG GYNECOLOGIC CANCER PATIENTS AT GEVERNMENT HOSPITALS IN BAHIRDAR; ETHIOPIA

PRINCIPAL INVESTIGATOR:

WALELIGN KINDIE (GYNECOCLOGIC ONCOLOGY FELLOW)

ADVISORS:

1. Dr. Eyaya Misgan (Associate professor of obstetrics and gynecology; Gynecologic oncologist)

2. Dr. Muluken Azage (Associate professor of water and public health)

RESEARCH THESIS SUBMISSION FORM

Full title of the research thesis	Health Related Quality Of Life Among Gynecologic Cancer Patients At Gevernment Hospitals In Bahirdar; Ethiopia
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Duration of the project	August to November,2024
Study area	Government hospitals at Bahirdar, Ethiopia
Total cost of the project	83,810 Ethiopia Birr

ASSURANCE OF INVESTIGATOR

I, the undersigned agree to accept responsibility for scientific, ethical and technical conduct of the research project and for provision of required progress reports as per terms and condition of the research and publications office of Bahirdar University.

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II

DECLARATION

I hereby declare that this research thesis is my original work and has not been presented for a degree in any other university, and all sources of material used for this work have been fully acknowledged.

Name: Dr. Walelign Kindie

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Date: _____

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First, I would like to thank Bahir Dar University, School of Medicine and Department of Gynecology and Obstetrics for giving me this opportunity to do this thesis research.

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ABSTRACT

Background:

The extent of health-related quality of life of gynecologic cancer patients varies between settings due to different factors at individual and health system level. There is paucity of information on magnitude of health-related quality of life and associated factors among gynecologic cancer patients in the study area. The available ones do have methodological limitations and use of arbitrary cut-off points to dichotomise quality of life into good and poor.

Objective: The objective of the study was to assess the magnitude of health related quality of life and associated factors among gynecologic cancer patients at government hospitals in Bahirdar, Ethiopia.

Methods: An institutional based cross-sectional study was conducted among gynecologic cancer patients at government hospitals in Bahirdar. The Amharic version of the European organization for research and treatment of cancer quality of life questionnaire core 30 versions 3 was used to asses health related quality of life. Epi-info version 4.6 and SPSS version 27 were used for data entry and analysis respectively. Descriptive statistics were used to describe the characteristics of the study participants. Binary logistic regression was conducted to identify factors associated with health related quality of life. Adjusted odds ratio at 95% confidence level was used to assess the strength of association and p values <0.05 was taken as statistically significant.

Result:

In this study, a total of 351 women diagnosed with any of the gynecologic cancers; and who fulfilled the inclusion criteria were included. The age of participants ranged from 19 to 76 years; with mean age 48 years (SD = ± 12.78 years. Majority couldn't read or write- 203(57.8%). Cervical cancer was the commonest (53.8%) type. The majority (136[38.7%]) were diagnosed to have stage IV cancer. Two hundred and twelve (60.4%) of the study participants were taking chemotherapy as the only treatment option.

In each of the five domains, the prevalence of affected quality of life was more than fifty percent; with Physical functioning being the most frequently affected domain of quality of life (85%).

Age (AOR=1.09, 95% CI: 1.07-1.18), pain (AOR=18.1, 95% CI: 3.56-93.72), type of treatment (AOR=0.04, 95% CI: 0.01-0.30) were associated with physical functioning status. Pain(AOR=6.50,95%CI:2.00-21.07),type of treatment(AOR=0.23,95%CI:0.09-0.59),occupation(AOR=3.68, 95% CI:1.12-12.08),cancer stage(AOR=3.68,95% CI:1.12-12.08),constipation(AOR=2.57, 95% CI: 1.17-5.63) and diarrhea(AOR=3.39, 95% CI: 1.50-7.70) were associated with role functiong.

Pain (AOR=10.39, 95% CI: 3.15-34.34), dyspnea (AOR=2.61, 95% CI: 3.15-34.34), sleep disturbance (AOR=2.32, 95% CI: 1.05-5.13) and appetite loss (AOR=2.69, 95% CI: 1.28-5.67)

were associated with emotional functioning. Constipation(AOR=3.13, 95% CI: 1.58-6.19) and financial impairment(AOR=3.92, 95% CI: 1.18-13.10) were associated with cognitive functiong, while pain(AOR=4.86, 95% CI: 1.50-15.78),dyspnea(AOR=6.08, 95% CI: 2.34-15.78),constipation(AOR=3.42, 95% CI: 1.02-11.50) and financial impairment(AOR=5.03, 95% CI: 1.48-17.04) were associated with social functioning.

Conclusion: The health related quality of life of gynecologic cancer patients in the study area is poor. The factors associated with the different functioning domains of quality of life emphasize the need for comprehensive; multidisciplinary approaches to deal with negatively affected quality of life in gynecologic cancer patients.

Key words: gynecologic cancer, Ethiopia, Health related quality of life, cross sectional prospective, European Organization for research and treatment of quality of life questionnaire.

ACRONYMS AND ABBREVIATIONS

AOR	Adjusted Odds Ratio
AP	Appetite Loss
CF	Cognitive Functioning
HPV	Hunan Papilloma Virus
CO	Constipation
COR	Crude Odds Ratio
DI	Diarrhea
DY	Dyspnea
EF	Emotional Functioning
EORTC QLQ-C30	European Organization for Research And Treatment Of Cancer Quality Of Life Questionnaire Core 30.
FA	Fatigue
FI	Financial Distress
HRQoL	Health Related Quality of Life
NV	Nausea and Vomiting
OPD	Outpatient Department
PA	Pain
PF	Physical Functioning
QOL	Quality Of Life
RF	Role Functioning
SD	Standard Deviations
SF	Social Functioning
SL	Sleep Disturbance
TCI	Threshold for Clinical Importance

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1. INTRODUCTION

1.1. Background

Cancer is a heterogeneous group of diseases characterized by the uncontrolled and unregulated division and growth of cells that can affect any part of the body(1).

Cancer is significant global health challenge. In 2020, there were an estimated 19.3 million new cancer cases and almost 10 million cancer deaths worldwide, making it the second leading cause of death worldwide (2).
Gynecologic cancer refers to a group of malignancies that originate in the female reproductive system, encompassing cancers of the ovary, endometrium, cervix, vagina, vulva, and trophoblastic disease. These cancers are significant health concerns, being the third most common cancer type and a leading cause of cancer-related deaths among women globally (3).

The most prevalent types include cervical, ovarian, and endometrial cancers, with cervical cancer being particularly lethal in developing countries due to its association with Human Papilloma Virus (HPV)(3).

The global trend of gynecologic cancers indicates a rising burden, with significant increases in both incidence and mortality rates over the past few decades. Forecasts predict that the burden will continue to rise over the next 20 years, with approximately 1.4 million new cases and 680,000 deaths reported in 2020(3, 4).

Notably, while the incidence of endometrial cancer has shown a significant global increase of 0.5% per year, mortality rates have declined by 0.8% annually. These trends reflect the complex interplay of socioeconomic factors, lifestyle changes, and advancements in diagnosis and treatment across different region(5).

Treatment modalities for gynecologic cancer include, surgery, chemotherapy, radiotherapy, targeted and immunotherapies, hormonal therapies, palliative care or a combination of these(6, 7). The goals of treating gynecological cancers include cure the cancer, control the disease, relieve symptoms, prevent recurrence, prevent fertility when possible and important and minimizing treatment side effects(8). Traditionally, the major outcome measure of gynecologic cancer treatment was survival. However, these days, maintaining or improving patients' health related quality of life are becoming equally important(9).

Although advances in screening techniques and anticancer therapies have increased long-term survival, neoplastic disease and associated treatments still have numerous physical and psychosocial consequences that deeply affect patients' quality of life(10).

The measurement of the health-related quality of life (HRQoL) in cancer patients includes the assessment of their subjective perception of symptoms, the side effects of treatments, and the consequences of the disease on various aspects of physical, role, emotional, cognitive, and social functioning (11, 12). The assessment of HRQoL in oncology represents is an important endpoint for clinical studies because there is a significant association between the overall quality of life, the domains of functioning, symptoms severity, adherence to treatments, and long-term survival. Routine measurement of the quality of life (QoL) in cancer patients is recommended in the USA and Germany(13, 14).

HRQoL is the subjective perception of the impact of disease and treatment on the health status of the patients that encompasses domains related to physical, functional, psychosocial or emotional functioning, that used to examine the impact of disease and its treatment on HRQoL(10, 15).

There are different tools, each with their own qualities and limitations, designed to measure the health related quality of life of cancer patients in general and gynecologic patients in particular(10, 16, 17).

The EORTC QLQ-C30 (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30) is a specific tool designed to assess the quality of life (QoL) in cancer patients. It stands out from other quality of life assessment tools in several key ways: it is developed for cancer patients and applicable to all cancer types. It offers a comprehensive multidimensional assessment, widely validated across different countries and languages making it a gold standard in oncology research. It includes items specifically related to cancer symptoms, such as fatigue, pain, and nausea, which may not be covered in general tools(18, 19). Thresholds for clinical importance are established to improve interpretation of the EORTQLQ-C30 in clinical practice and research(20).

1.2. Statement of the problem

The health-related quality of life (HRQoL) among women diagnosed with gynecological cancer is a critical concern, as these patients often experience significant psychological and physical challenges during their treatment journey. Despite advances in treatment care, many women undergoing different modalities of treatment report poor HRQoL, which is influenced by a myriad of socio-demographic factors such as education, income, marital status, and age (21).

Specifically, women with no or low level of education and those from low resource settings are more vulnerable to the impacts of poor health related quality of life(22).

The problem of poor quality of life is especially worrisome among adolescents and young adults as these segment of patients have special concerns related to loss of fertility, early loss of body image, sexual dysfunction and other endocrine functions because of premature ovarian failure(23, 24).

The magnitude of poor health related quality of life among gynecologic cancer patients varies in different parts of the world: A study done among 225 gynecologic cancer patients in India showed that about 17% of the cases did have poor health related quality of life; while 72.8 % cases had moderate quality of life(25). The prevalence of poor health related quality of health among Cancer patients in general in Ethiopia ranges from 52-89.6% while 60% -65% of postsurgical cervical patients developed anxiety /depression (26, 27).

The problem of sexual dysfunction among survivors of endometrial and cervical cancer patients reaches 85%- 94% leading to divorce and breakdown of family and children (28, 29).

The impact of poor health related quality of life on financial status is of at most important for gynecologic cancer patients. Many survivors report difficulties in professional reintegration, with 34% indicating a negative impact on their work capabilities(30).

Low QoL is associated with undesirable treatment outcomes, such as mental illness, i.e., anxiety, depression, and hopelessness, which may lead to non-adherence to treatment gradually, worsen the prognosis and increase mortality rates (9, 31, 32).

Although QOL has traditionally been examined as an outcome, it has also been considered as a predictor of survival. Hence, QOL and other patient reported outcomes (PRO) measures can identify cancer patients most a risk of subsequent health problems. Identification of at risk survivor populations can guide the allocation of supportive care measures during and after cancer treatment(33).

As to the best of my knowledge, there is no study about HRQoL among gynecologic cancer patients in the study area. Those done in other areas in the country do have a different set up and different study populations (34). For example, the absence of radiotherapy in our setting may be associated with a worse HRQoL as compared to other areas; necessitating the conduct of our study. The socioeconomic status of study participants which has an impact on HRQoL is also varied. Those done in similar settings do have a methodological gap (35). Most importantly, they used arbitrary cut-off points to the EORTQLQ-C30 HRQoL scores and hence the clinical and research utility of the findings of such studies is questionable. In this study standardized cut off points set by the EORT Quality of life group was implemented (20). Therefore, this study was conducted to assess health-related quality of life and associated factors among gynecologic cancer patients in government hospitals in Bahirdar, northwest Ethiopia.

1.3. Significance of the study

The findings of this study will be primarily important for the practicing physician. Pretreatment determination of the HRQoL score of patients will help the clinicians to plan an individualized treatment approaches.

For policy makers, the findings of this study, may contribute an input in the consideration for the possible incorporation of assessment of HRQoL of gynecologic cancer patients into national cancer treatment guidelines.

For researchers and the other scientific community, this study will serve as a basis to conduct further multicenter study on large scale setting including interventional studies. It will also help the scientific community to build up its knowledge about the rising issue of quality of life of cancer patients.

2. LITERATURE REVIEW

2.1. Prevalence of QoL and HRQoL domain scores

Analysis of health related quality of life data among survivors of cervical cancer patients in United States of America showed that 25 % of the cases do have low physical health as compared to adults with no cancer history (10% and 5%). In this study, 26% and 28% of the cervical cancer survivors did have depression and anxiety problems respectively(33).

A study done in Nigeria showed that prevalence of depression and anxiety among gynecologic cancer patients is 25.3% and 8.8 % respectively(36).

Regarding the EORTC QLQ-C30 functioning subscales a study done in Italy showed that most of the patients show a good level of functioning scales (physical functioning's median = 93.33; role functioning's median = 100; emotional functioning's median = 83.33; cognitive functioning's median = 100; social functioning's median = 100)(37).

A study HRQoL study done in Addis Ababa showed that, the mean Global Health Status (global quality of life) score was 40.95(SD ± 24.35) and of the functional scales, social function 42.26 (SD±32.08), was the most affected domain followed by role function 50.12 (SD±35.11) whereas cognitive function is least affected (mean= 88.21, SD ± 18.49). The highest score on the symptom scale was for financial difficulties (mean=64.76, SD ± 32.43) followed by pain (mean=55.12, SD ± 29.64) and fatigue (mean=53.97, SD ± 28.54) while the lowest score was for diarrhea (mean=1.19, SD ±7.38)(34).

2.2. Factors associated with HRQoL among gynecologic cancer patients

Health-related quality of life (HRQoL) among gynecologic cancer patients is influenced by a variety of factors, including socio-demographic, psychological, and treatment-related aspects. Understanding these factors is crucial for improving patient care and outcomes (38).

Sociodemographic and economic factors:

Age is one of the most important factors affecting HRQoL of gynecologic cancer patients. Both younger age and older age are associated with lower quality of life among gynecologic cancer patients (39).

Studies from Turkey showed that being single is associated with higher emotional and social scores, while role function scores were better among married ones(40). A study in Dessie,

Ethiopia come with a different association of marital status and HRQoL in that patients who are married, as compared to singles, have lower total QOL scores.

With respect to occupation, a study in Kenya reported vulnerable groups for poor HRQoL as those who are peasant farmers or casual workers. Full-time employment (before and during therapy) appear to be protective factors and predictors of a better short-term quality of life(37).

A study done in Dessie, Ethiopia showed that education to secondary school and above is associated with good QoL (35). Perceived social support, especially from friends and families are associated with better quality of life(37).

Studies from different setting said that better monthly income is associated with better quality of life(41, 42). Besides, a study in Malaysia, showed that gynecologic cancer patients who had medical insurances had better health related quality of life as compared to those who are paying(43).

Clinical factors

A quality of life study at Gazi University in Turkey revealed that women with ovarian cancer had the highest while women with cervical cancer had the lowest global health score (65.3 ± 24.7 and 43.0 ± 24.1, respectively)(40). Women with endometrial cancer were found to have better role function, and social wellbeing than those with vulvar, cervical or ovarian cancer.

A research conducted in France in France revealed that Concerns and worries about chemotherapy outcome, side effects, and risk of relapse may affect the ability of patients to perform the usual social and domestic roles. Survivors of gynecological cancer who had comorbidities, or had been hospitalized within the last 12 months had worse HRQoL (44).

A study in Dessie showed that patients with ovarian and endometrial cancers had higher physical, social, psychological and total QOL scores compared to those with cervical and vulva cancers(41).

As to the result of the above study, global, physical, role function, cognitive and social scores were found higher in women who had been treated with surgery(40). A different study in the same country showed that those receiving radiation and chemotherapy had significantly poor physical and social functioning(45).

3. CONCEPTUAL FRAMEWORK

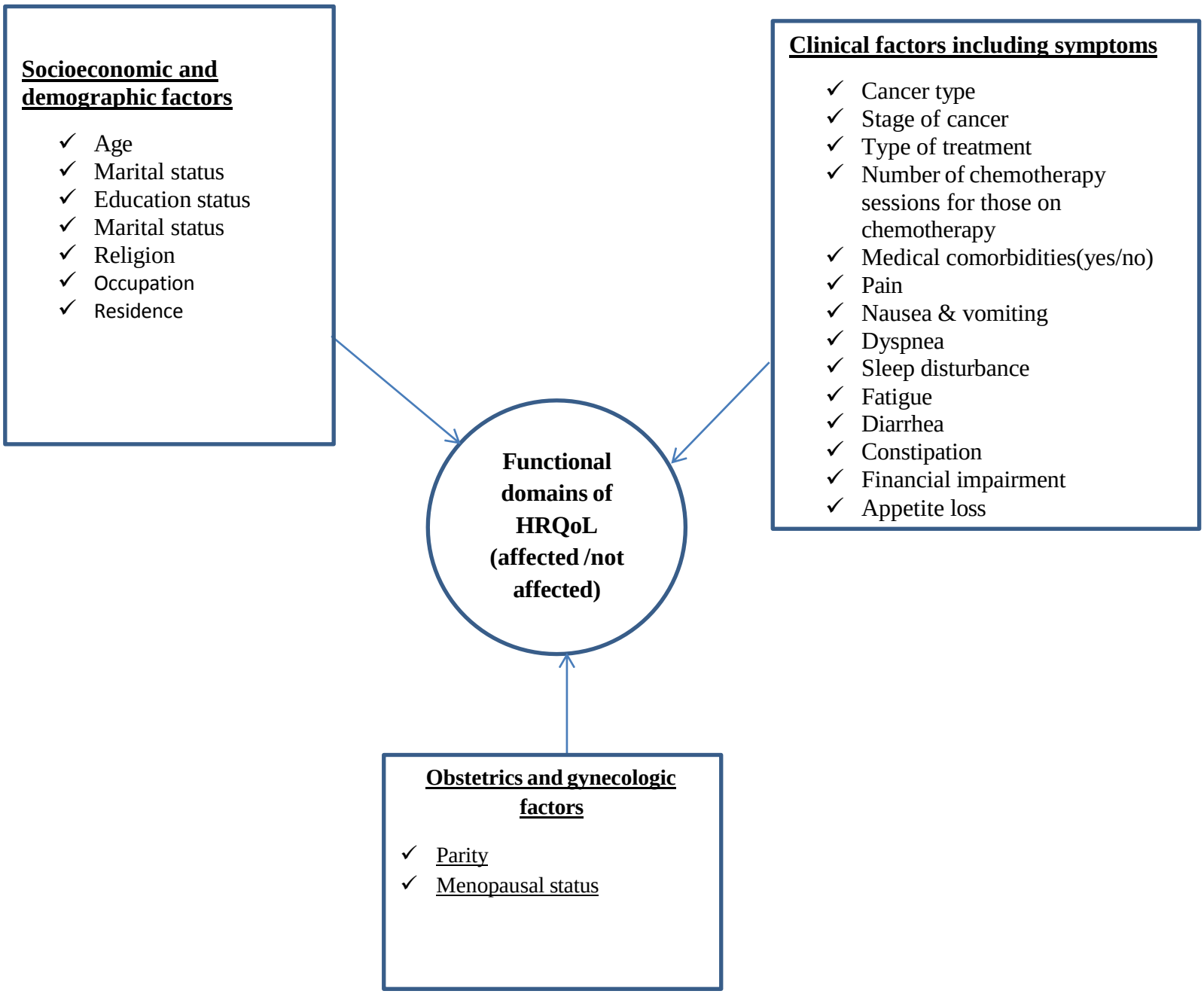

Figure 1conceptual frameworkshowing factors associated with health related quality of life among gynecologic cancer patients at government hospitals in baj=hirdar:(fcators are collected from literature review)

4. OBJECTIVE

4.1. General objective

The general objective of this study is to assess health related quality of life and associated factors among gynecologic cancer patients attending cancer treatment centers at Bahirdar, northwest Ethiopia,2024

4.2. Specific objectives

1. To determine health related quality of life among gynecologic cancer patients
2. To identify factors associated with health-related quality of life among gynecologic cancer patients.

5. METHODS AND MATERIALS

5.1. Study area

The study was conducted at Tibebe Ghion comprehensive specialized hospital (TGCSH) and Felege Hiwot comprehensive Specialized Hospital (FHCSH) where oncologic services are there. The two hospitals are the only specialized hospitals in Bahirdar city- the Capital City of Amhara National Regional state, located 565 km Northwest of Addis Ababa with estimated population of 168,899 as per 2022 world population review(46). The city has two tertiary hospitals, 1 primary Hospital, four private general hospitals, 6 health centers, 13 private clinics, 2 Non government clinics, one Fistula center and one regional public health institute. Both TGSH and FHCSH have an estimated catchment population of seven million. FHCSH is officially started its function in 1965 G.C while TGSH started giving service from 2019 G.C. Both Hospitals are providing medical oncology services for cancer patients in general and surgical oncology services for gynecologic cancer patients in particular. In that regard, there are two clinical oncologists, two gynecologic oncologists and two gynecologic oncology fellows working at both sites.

5.2. Study design and period

The study employs a cross sectional study design which will be conducted from September 2024 to November 2024.

5.3. Population

5.3.1. Source population

The source population includes all cases of women who visit the two hospitals for medical care and diagnosed with gynecologic malignancies.

5.3.2. Study population

The study population includes all gynecologic cancer cases getting clinical services during the study period

5.4. Eligibility criteria

5.4.1. Inclusion criteria

Gynecologic cancer patients with all of the following features can be included in the study

1. Subjects who are diagnosed with the gynecological cancers confirmed by histopathology.
2. Subjects who are going to start definitive treatment, or are on treatment or completed treatment.

5.4.2. Exclusion criteria

Those cases with any one of the following features will be excluded from participating in this study

1. Subjects who are unable to communicate because of severe illness
2. Those with a diagnosed psychiatric disorders
3. Those cases with other diagnosed non gynecologic cancers like breast, colon, lung cancer etc.
4. Gynecologic cancer patients started on treatment at other centers and referred to the study areas for post treatment follow up service only.

5.5. Study variables

Dependent variables:

HRQoL (functional domains) (affected /not affected)

Independent variables:

Sociodemographic factors:

Age

Marital status

Educational status

Occupation

Residence

Religion

Obstetrics factors & gynecologic factors:

Parity, menopausal status

Clinical factors:

Cancer type

Duration of diagnoses

Stage of cancer

Type of treatment

Comorbidity (yes/no)

Symptoms (pain, fatigue, nausea vomiting, insomnia, diarrhea, constipation, appetite loss, financial impact)

5.6. Operational and term definitions

Health related quality of life : is the subjective perception of the impact of disease and treatment on the health status of the patients that encompasses domains related to physical, functional, psychosocial or emotional functioning, that used to examine the impact of disease and its treatment on HRQoL.

Positive (affected) quality of life – In this study positive or affected quality of life refers to functioning domains of health related quality of life scoring below their corresponding cut off points, implying decreased functioning. For symptom domains, this refers to symptom scale scores above their respective cut off point, indicating worsening of symptoms (see table 1).

Negative (not affected) quality of life – refers to normal functiong (score above the corresponding cut off point) or symptom that is not worrisome and doesn't need to be treated (score above the corresponding cut off point).

5.7. Sample size determination

The sample size (n) for this study was determined using single population proportion formula by considering the following assumptions: taking confidence level of 95% (1.96), d-the margin of error (0.05), and 50% of the proportion of HRQoL since there is no previous study with the same study tool. The calculated sample size is 384. Considering 5 % non-response rate, the final sample size will be 384/0.95=404.

5.8. Sampling Technique and procedure

A six month medical oncology and gynecologic outpatient department(OPD) patient registration audit at both hospitals showed that the average number of gynecologic cancer patients (excluding repeated visits and intrafacilty transfers between medical and gynecologic oncologic clinics) is 174 per month (97 at Tibebe Ghion and nearly 77 at Felege Hiwot Specialized hospitals). (This figure might be a bit exaggerated as there could be interfaculty transfers between the two hospitals).

Therefore, over three months, the expected total number of gynecologic cancer clients would be about 522.

To use a systematic random sampling technique, over three months, the sampling interval (K) would be 522/404=1.29. Because of time constraint, all cases that fulfilled the inclusion criteria were consquetively included in the study.

Using the principle of proportional allocation, of the total 404 study participants, 178(44%) were planned to be from Felege Hiwot hospital while the remaining 228(56 %) from Tibebe Ghion specialized hospital.

5.9. Data collection instruments and procedures

The data collection tools include well-structured interviewer administered questionnaire, check lists and the European Organization for Research and Treatment Quality of Life Questionnaire version 3 (EORT QLQ-C30).

Measuring HRQoL -The EORTC QLQ-C30 tool

The EORTC QLQ-C30 is designed for use with a wide range of cancer patients and has been translated and validated in over100 languages, including Amharic. The tool was valid and reliable in Ethiopia. The EORTC QLQ-C30 is the main questionnaire that is aimed at addressing the health-related quality of life (QoL) of cancer patients. It incorporates 30 items that can be incorporated into 15 scales; among which five are functional scales (physical (PF), role(RF), cognitive(CF), emotional(EF), and social functioning(SF)); three symptom scales (fatigue(FA), pain(PA), and nausea or vomiting(NV)); a two-item global QoL scale(QL); and six single item scales (dyspnea(DY), appetite loss(AP), sleep disturbance(SL), constipation(CO), diarrhea(DI), and financial impact of disease(FI)). For all scales, item scores are summarized and linearly transformed into a score ranging from0-100.Higher scores on the functioning scale indicate higher level of functioning, whereas higher scores on the symptom scale indicate more symptom burden.

The technical summary regarding to the principle of scoring of these scales is stated at Annex 3.

Regarding to the procedure of data collection, data were collected from clients at gynecologic and medical oncologic clinics of the two hospitals. Clients will be assigned serial number starting from 1 based on their order of arrival to the Oncologic clinics. After taking informed consent, socio demographic data was obtained using the interviewer administered well-structured questionnaire- developed after a thorough review of literatures on the topic. Data about health related quality of life of patients were collected using the Amharic version of the EORT QLQ-C30. Finally, data about clinical parameters like type and stage of cancer, type of treatment and duration of treatment were extracted from patients' charts using check list.

5.10. Data management and analysis

After collection, data were entered and cleaned in Epi- info version 7 and, then it was exported to Statistical package for social sciences (SPSS) version 27 soft for analysis. Descriptive statistics like frequency, proportions, means and standard deviation were computed.

Binary logistic regression analysis was conducted to explore factors associated with HRQoL.

During the univariable logistic regression analysis, all variables with p<0.25 were included in the multivariable logistic regression. AOR with their respective confidence interval (CI) at 95% confidence level were used to assess the presence of any association between the independent and outcome variables. Independent variables with P values < 0.05 were considered as statistically significant.

For the purpose of analysis, each outcome variable was dichotomized using the "thresholds for clinical importance''(TCI) for each of the HRQOL domains of EORTQLQ-C30 which was provided by the EORT Quality of Life Group study in 2022. Scores below the TCI for functioning scales, or above the TCI for symptom scales indicate clinically important problems or symptoms and are designated as "affected (positive) QoL domain" in this research.

Table 1 : threshold for clinical importance(TC) for the functioning and symptom scales of the EORTC QLQ-C3O(47)

Functioning scales:	TCI	**Symptom scales**	TCI
Physical Functioning (PF)	83	Fatigue	39
Role Functioning (RF)	58	Pain	25
Social Functioning (SF)	58	Nausea/vomiting	8
Emotional Functioning (EF)	71	Sleep disturbance	50
Cognitive Functioning (CF)	75	Dyspnea	17
		Appetite loss	50
		Constipation	50
		Diarrhea	17
		Financial impact	17

5.11. Data quality control

Data were collected by 3 Bachelor of sciences (BSc) nurses who have special training on clinical oncology; and supervised by two medical oncologists and residents. Data collectors were given 3 day training on contents of the questionnaire and data collection methods. Every filled check list was seen by the supervisors and principal investigator for consistence and completeness.

5.12. Ethical considerations

Before the start of the actual data collection, ethical clearance letter was obtained from the institutional board of the College of Medicine and Health Sciences of Bahirdar University.

Letter of collaboration and ethical clearance, obtained from institutional board of College of medicine and health sciences of Bahirdar University, was submitted to Tibebe Ghion- and Felege Hiwot- Specialized Hospitals. Letter of permission was obtained from the hospitals clinical directors' offices. Each chosen study participant was asked to give us a verbal agreement after the study's goal has been presented. Additionally, participants were made

aware that their involvement in the study is entirely optional, that they have the right to discontin ue at any time, and that their choice to participate or not didn't not have any bearing on the provi sion of healthcare services. We omitted personnel identifiers throughout the data collection and, collected data were stored in a lockable cabinet and data entered into SPSS were password protected, access to data was restricted to the research team only.

5.13. Dissemination plan

The findings of this study will be delivered to Bahirdar University College of Medicine and Health Science, School of medicine and department of obstetrics and gynecology. Besides, it will be delivered to the two hospitals (Tibebe Ghion- and Felege Hiwot- specialized hospitals) and the regional health bureau. The findings will also be presented at different conferences, seminars and workshops. It will be communicated to other interested parties and organizations as well. Last it will be published in local or international Journals to make it available to the scientific community.

6. RESULTS

6.1. Socio-demographic, gynecologic and obstetrics characteristics

In this study, a total of 351(86.8% of the estimated sample size) women with a histologic proven diagnosis of gynecologic cancers were participated in the survey. The age of participants ranged from 19 to 76 years with mean age of 48 years (SD = ± 12.78 years). Majority, 203(57.8%), can't read or write; while only 45 (12.8%) have achieved college and above level of education. One hundred sixty six (47.3%) of the participants are married. In terms of religion and residence, 323 (92.0%) are orthodox Christianity followers; and 185(52.7%) came from rural areas respectively.

With respect to occupations, while 149(42.5%) are farmers, a quarter, 87 (24.8%) are housewives. One hundred and ninety seven (56.1%) of the study participants are in postmenopausal age.

Table 2: Socio demographic, gynecologic and obstetrics charactetstics of women with gynecologic cancers at government hospitals in Bahirdar, Ethiopia from September to December, 2024 (N=351).

Variable	Category	Frequency	Percent
Level of education	illiterate	203	57.8
	primary	69	19.7
	secondary	34	9.7
	college and above	45	12.8
Residence	Urban	166	47.3
	rural	185	52.7
Religion	orthodox	323	92.0
	Muslim	28	8.0
Marital status	single	14	4.0
	married	166	47.3
	divorced	28	8
	widowed	48	13.7
Occupation	Farmer	149	42.5
	Gov't	43	12.3
	Private	65	18.5
	Student	4	1.1
	Unemployed	3	0.9
	House wife	87	24.8
Parity	0	25	7.1
	1-4	160	45.6
	5-9	166	47.3
	10+	12	3.4

Menopausal status	premenopausal	154	43.9
	Postmenopausal	197	56.1

6.2. Clinical charactetstics related factors

The distribution of gynecological cancers in the data reveals a notable predominance of cervical cancer, accounting for 189 cases, which represents 53.8% of the total. Ovarian cancer follows with 85 cases, making up 24.2% of the occurrences. Endometrial cancer and vaginal cancer are significantly less prevalent, with 3 cases (0.9%) and 5 cases (1.4%), respectively.

The data on the stages of cancer indicates that the majority of cases are diagnosed at stage IV, with 136 instances, accounting for 38.7% of the total. Stage II follows, with 84 cases, representing 23.9%. Stage I has the fewest diagnoses, with 59 cases, making up 16.8% of the total.

The distribution of participants by treatment modality showed that chemotherapy is the most common treatment, with 212 patients, comprising 60.4% of the total. Surgery is a less frequent choice, used in 43 cases, representing 12.3%. There are also 38(10.8 %,) cases, for whom treatment had not yet been initiated.

Table 3: clinical charactetstics of women with gynecologic cancers at government hospitals in Bahirdar, Ethiopia from September to December, 2024 (N=351).

Variable	Category	Frequency	Percent
Type of cancer	Cervical	189	53.8
	ovarian	85	24.2
	Vulvar	33	9.4
	GTN	36	10.3
	Endometrial	3	0.9
	Vaginal	5	1.4
Stage of cancer	I	59	16.8
	II	84	23.9
	III	72	20.5
	IV	136	38.7
Type of treatment	Chemotherapy	212	60.4
	Surgery	43	12.3
	Both	58	16.5
	Rx not started	38	10.8
Any known medical comorbidity	No	280	79.8
	Yes	71	20.2

6.3. "Prevalence" of affected quality of life scores

When we see the functioning domains of quality of life, more than half of the participants have impaired functioning status in each domain, with the most prevalent affected domain being physical function where 300(85.5%) participants have clinically significant impairment in their physical performance; followed by social function, 283(80.6%).Cognitive function is the least affected domain, where 182(51.9%) women are with different degree of cognitive impairment.

When examining the symptom domains of quality of life, more than half of the participants in five out of the nine symptom domains exhibit clinically significant symptoms. Financial impairment with 318 participants (90%) and pain with 309 participants (88%) are the most frequent symptomatic domains. Diarrhea is the less frequent clinically significant domain of quality of life, 75(21.4%).

There is no standard cut off point to determine the prevalence of affected global/overall health status. Analysis of this data showed that the mean Global QoL score is 50.17SD (SD= ±24.71).

Table 4: "prevalence" of affected quality of life across each domains of quality of life among women at government hospitals in Bahirdar, Ethiopia from September to December, 2024 (N=351).

Symptom scale	Category	N	%	**Functioning status**	Category	N	%
FA	Negative	78	22.2	PF	Negative	51	14.5
	Positive (Score ≥39)	273	77.8		Positive (Score ≤ 83)	300	85.5
NV	Negative	116	33.0	RF	Negative	121	34.5
	Positive (Score ≥8)	235	67.0		Positive (Score ≤ 58)	230	65.5
PA	Negative	42	12.0	EF	Negative	100	28.5
	Positive (Score ≥25)	309	88.0		Positive (Score ≤ 71)	251	71.5
DY	Negative	191	54.4	CF	Negative	169	48.1
	Positive (Score ≥17)	160	45.6		Positive (Score ≤ 75)	182	51.9
SL	Negative	191	54.4	SF	Negative	68	19.4
	Positive (Score ≥50)	160	45.6		Positive (Score ≤ 58)	283	80.6
AP	Negative	175	49.9	**Global QoL scale**	Mean:50.17(SD=±24.71) Range :0.0-100.0		
	Positive (Score ≥50)	176	50.1				
CO	Negative	262	74.6				
	Positive (Score ≥50)	89	25.4				
DI	Negative	276	78.6				
	Positive (Score ≥17)	75	21.4				
FI	Negative	33	9.4				
	Positive (Score ≥17)	318	90.6				

6.4. Factors associated with health related quality of life

Binary logistic regression was done to identify statistically significant factors associated with the outcome variables, which are PF, RF, EF, and CF & SF. By controlling confounding variables using multivariable binary logistic regression, we found variables like age, occupation, pain, cancer stage, constipation, diarrhea, sleep disturbance, financial impairment, type of treatment and loss of appetite to be associated with the different outcome variables.

6.4A. Factors associated with physical functioning

Controlling all other variables constant, the odds of developing affected physical function is 1.09(AOR=1.09, 95% CI: 1.07-1.18) times more likely for every one year increment in age.

The odds of developing physical function limitation is 0.04(95% CI: 0.01-0.30) times less likely in those who are managed surgically or doesn't start any treatment as compared to those who are managed with chemotherapy.

The probability of having clinically significant physical function limitation is 18 times (95% CI: 3.56-93.72) more likely in those with pain than those not.

6.4B. Factors associated with Emotional functioning & cognitive functioning

Presence of pain, dyspnea, insomnia and appetite loss are statistically associated with affected emotional functioning. Those with pain as compared to those with not are 10 times (95% CI: 3.15-34.34) more likely to have disturbance in emotional functioning. Keeping all other factors constant, patients with appetite loss are 2.69(95% CI: 1.28-5.67) times more likely to have emotional liability as compared to those with normal appetite.

Gynecologic cancer patients having constipation are 3.13(95% CI: 1.58-6.19) times more likely to develop cognitive impairment than those without constipation. The odds of developing impaired cognitive functioning is 3.92(95% CI: 1.18-13.10) times higher among those with financial impairment than those with no financial problem.

6.4C. Factors associated with Role & social functioning

Housewives are 3.68(95% CI: 1.12-12.08) times more likely to lose their role functioning as compared to those who are government employees. When we see with respect to stage of cancer, those with stage II are 3.17(95% CI: 1.16-8.67) times more likely to have decreased role function as compared to those with stage I gynecologic cancer. Gynecologic cancer patients who do not start any treatment are 77% less likely (AOR= 0.23, 95%CI: 0.09-0.59) to develop impairment in their role functioning compared to those with stage I cancer patients. The odds of developing role limitation in those with diarrhea as compared to those without is 3.39(95% CI: 1.50-7.70) times higher. Constipation and pain are also associated with limitation in role functioning.

Participants with dyspnea are 6(95% CI: 2.34-15.78) times more likely to have a decrement in social functioning than those with no dyspnea. The odds off developing affected social function among those with pain than those without is 4.86(95% CI: 1.50-15.78) times higher.

Keeping other factors unchanged, constipation increases the probability of social function limitation by 3.42(95% CI: 1.02-11.50) times. Financial impairment is also an important factor associated with decreased social functioning (AOR=5.03, 95% CI, 1.48-17.04).

Table 5: table showing multivariable logistic analysis of factors associated with functional status domains of health related quality of life among gynecologic cancer patients(N=351), TGSCH & FHCS, 2024.

Variable	Physical functioning			
	Affected	**Not affected**	**COR (95% CI)**	**AOR(95% CI)**
Age	----	----	1.04(1.02-1.07)	1.09 (1.07-1.18)*
Type of Rx				
Chemo	200	12	1	1
Surgery	20	23	0.05(0.02-0.12)	0.04(0.01-0.30)**
Both	58	0	---	---
None	22	16	0.08(0.04-0.19)	0.04(0.01-0.23)***
Pain				
Yes	288	21	34.3(15.36-76.5)	18.1(3.56-93.72)***
No	12	30	1	1
Variable	**Emotional functioning**			
	Affected	**Not affected**	**COR (95% CI)**	**AOR(95% CI)**
pain				
Yes	244	65	18.77(7.97-44.19)	10.39(3.15-34.34)***
No	7	35	1	1
Dyspnea				
Yes	135	25	3.49(2.08-5.85)	2.61(1.26-5.41)**
No	116	75	1	1
Insomnia				
Yes	125	30	2.32(1.41-3.79)	2.32(1.05-5.13)*
No	126	70	1	1
Appetite loss				
yes	148	28	3.70(2.23-6.12)	2.69(1.28-5.67)*
No	103	72	1	1
Variable	**Cognitive functioning**			
	Affected	**Not affected**	**COR (95% CI)**	**AOR(95% CI)**
constipation				
Yes	64	25	3.12(1.82-5.26)	3.13(1.58-6.19)**
No	118	144	1	1
Financial impairment				
Yes	177	141	7.03(2.65-18.67)	(3.92(1.18-13.10)*
No	5	28	1	1

Variable	Role functioning			
	Affected	Not affected	COR (95% CI)	AOR(95% CI)
occupation				
Government	18	25	1	1
housewife	66	21	4.36(2.00-9.52)	3.68(1.12-12.08)*
farmer	109	40	3.78(1.87-7.67)	---
others	37	35	---	---
FIGO stage				
stage I	22	37	1	1
stage II	61	23	4.46(2.19-9.10)	3.17(1.16-8.67)**
stage III	47	25	3.16(1.54-6.47)	----
stage IV	100	36	4.67(2.44-8.96)	----
Type of Rx				
Chemo	157	55	1	1
Surgery	14	29	0.17(0.08-0.34)	---
Both	43	15	---	---
None	16	22	0.26(0.13-0.52)	0.23(0.09-0.59)**
Pain				
Yes	225	84	19.82(7.52-52.11)	6.50(2.00-21.07)**
No	5	37	1	1
Constipation				
Yes	74	15	3.35(1.83-6.15)	2.57(1.17-5.63)*
No	156	106	1	1
Diarrhea				
Yes	61	14	2.76(1.47-5.18)	3.39(1.50-7.70)
No	169	107	1	1
Variable	**Social functioning**			
	Affected	**Not affected**	**COR (95% CI)**	**AOR(95% CI)**
Pain				
Yes	271	38	17.83(8.42-37.77)	4.86(1.50-15.78)*
No	12	30	1	1
Dyspnea				
Yes	150	10	6.54(3.21-13.31)	6.08(2.34-15.78)***
No	133	58	1	1
Constipation				
Yes	81	8	3.01(1.38-6.57)	3.42(1.02-11.50)*
No	202	60	1	
Financial impact				
Yes	273	45	13.95(6.23-31.24)	5.03(1.48-17.04)*
No	10	23	1	1

Note: Significant at p-value <0.05= *, P- value ≤0.005 = **, p-value ≤0.001 =***

7. DISCUSSION

Because this study is the first in its kind after the development of cutoff values for the domains of quality of life of the EORT QLQ-C30 tool, there are no similar studies to compare the results with. Hence, the discussion part will focus mainly on elaborating the meaning of the results, stating their significance and major patterns in the observation.

In this study, when we see the "prevalence" of affected quality of life, among functioning scales PF and SF ranked 1st and 2nd. A study done at Tikur Anbesa Specialized hospital, Addis Ababa also comes up with similar result, with the exception in that SF ranks 1st and PF ranks 2nd. Of the symptom scales, financial impairment and pain took the first positions in order. The Tikur Anbesa Specialized hospital study also showed similar results. Of the symptom scales, diarrhea is the least prevalent one in both studies(48).

It's interesting to see the consistency in findings between two studies. The fact that Physical Functioning (PF) and Social Functioning (SF) are consistently ranked high in terms of prevalence among the functioning scales highlights the significant impact these aspects have on the quality of life for patients with gynecologic cancers. Similarly, the consistency in financial impairment and pain being the top symptom scales across the studies, underscores the universal challenges faced by these patients.

Such findings can provide valuable insights for healthcare providers and policymakers to prioritize interventions and support systems to improve the quality of life for these patients.

The findings from this study highlight several important factors influencing the development of physical function limitations.

Firstly, the analysis demonstrates that age is a significant predictor of physical function impairment. Specifically, for every one-year increase in age, the odds of developing an affected physical function increase by 1.09 times. A study in turkey also came up with a similar finding in that younger age associated with higher score in Physical functioning(49). This result underscores the impact of aging on physical capabilities, which is consistent with the fact that aging is associated with a decline in physical function due to factors like muscle deterioration, joint stiffness, and reduced mobility.

Additionally, the study reveals that treatment modality plays a crucial role in physical function outcomes. The odds of developing physical function limitations are significantly lower (0.04 times lower) in individuals managed surgically or those who have not started treatment, compared to those undergoing chemotherapy. A somewhat related study done in Turkey among women with gynecologic cancers, showed that chemotherapy is also associated with decreased functional quality of life scores(49).A study among 251 Iranian women with gynecologic cancers also showed that those who are managed surgically hade better physical functiong than those managed with chemotherapy(50). These finding suggests that chemotherapy may have a more debilitating effect on physical function, possibly due to its associated side effects such as fatigue, muscle weakness, and neuropathy.

Pain is another important influential factor of physical functioning, with individuals experiencing pain being 18 times more likely to develop clinically significant physical function limitations compared to those without pain. This substantial increase highlights the severe impact of pain on physical capabilities, likely due to pain-related movement restrictions and the adverse effects of chronic pain on overall health. Addressing pain effectively is essential to improving physical function and quality of life in affected individuals.

The study also highlights several key factors that are significantly associated with emotional and cognitive functioning in gynecologic cancer patients.

Firstly, the presence of pain, dyspnea, insomnia, and appetite loss are all statistically linked to impaired emotional functioning. Notably, patients experiencing pain are 10 times more likely to suffer from emotional disturbances compared to those without pain. A systematic review of 10 studies showed that pain, appetite loss and dyspnea are associated with decreased general quality of life, as well as emotional functioning of cancer patients(51). This finding aligns with existing literature that underscores the profound impact of chronic pain on emotional well-being, likely due to the persistent stress and discomfort it causes.

Appetite loss also emerged as a significant predictor of emotional instability. Patients with appetite loss are 2.69 times more likely to experience emotional liability compared to those with a normal appetite. This suggests that nutritional status may play a crucial role in emotional

health, possibly through mechanisms involving energy levels, nutrient deficiencies, and overall physical health.

In addition to emotional functioning, the study found that cognitive impairment is more likely among patients experiencing certain symptoms and socioeconomic challenges. Specifically, gynecologic cancer patients with constipation are 3.13 times more likely to develop cognitive impairment than those without constipation. This finding highlights the potential impact of gastrointestinal symptoms on cognitive function, possibly through mechanisms related to discomfort and overall well-being.

Moreover, financial impairment significantly increases the likelihood of cognitive dysfunction. Patients facing financial challenges are nearly four times more likely to suffer from cognitive impairment compared to those without financial problems. This association may be due to the stress and mental burden associated with financial difficulties, which can exacerbate cognitive issues and affect overall mental health.

Similar to the physical, emotional and cognitive functioning, there are important factors associated with role and social functioning.

Firstly, employment status emerges as a crucial determinant of role functioning. Housewives are 3.7 times more likely to lose their role functioning compared to government employees. A related study in Kenya also showed that government employees had higher scores in functioning and global quality of life domains score(41). This disparity physical functiong with respect to occupation status may be attributed to varying levels of support systems, physical demands, and psychological impacts associated with different occupational roles. For example, housewives might be engaged in physically demanding tasks as compared to government employees; and they may not have any one around to help them. When considering the stage of cancer, those diagnosed with stage II gynecologic cancer are 3 times more likely to experience decreased role function than those with stage I cancer. This suggests that as the disease progresses, its impact on daily activities and responsibilities becomes more pronounced.

Interestingly, patients who have not started any treatment are 77% less likely to develop role impairment compared to those who are on chemotherapy. Chemotherapy is associated with limitations in role functioning for several reasons. For example, chemotherapeutic drugs are

associated with toxic side effects (nausea, vomiting, fatigue, neuropathy etc) which can significantly impair a patient's ability to perform daily activities and fulfill their roles at home, work, or in social settings. Chemotherapies can bring physical weakness making it difficult for patients to engage in routine tasks and responsibilities. Some chemotherapy drugs can cause cognitive issues, which includes memory problems and difficulty concentrating, further hindering a patient's ability to function effectively in their roles. The other important reason could be due to treatment burden. The frequent medical appointments, hospitalizations, and the overall burden of the treatment schedule can disrupt a patient's normal routine and responsibilities, making it challenging to maintain their usual roles.

Symptom burden plays a pivotal role in functional limitations. The odds of developing role limitations are 3.4 times higher for patients with diarrhea compared to those without. Additionally, constipation and pain are also linked to role functioning limitations, emphasizing the need for effective symptom management.

Regarding social functioning, participants with dyspnea are six times more likely to experience a decline in social interactions compared to those without dyspnea. Pain similarly increases the likelihood of impaired social functioning. These findings underscore the profound impact of physical symptoms on patients' social lives and their ability to maintain relationships and participate in social activities.

Constipation further increases the probability of social function limitation by 3.4 times highlighting its significant role in diminishing social well-being. Financial impairment also emerges as a key factor, with those experiencing financial difficulties being 5 times more likely to suffer from decreased social functioning.

8. STRENGTHS AND LIMITATIONS OF THE STUDY

8.1. Strength of the study

The study uses a primary data source making it complete and more reliable.

The other strength of this study is that, as to the knowledge of the researcher, it is the first study in Ethiopia, after development of cutoff points for the quality of life domains in the EORTQLQ-C30 tool. So that its utility in clinical as well as in research area will pronounced.

8.2. Limitation of the study

This study has also limitations.

Because of time constraint, the sample size is smaller than it was planned.

Another limitation of the study is that, it employed a cross sectional way of data collection, making to know the temporal relation of the factor and the outcome difficult.

9. CONCLUSION

This study underscores the significant impact of various factors on the physical, emotional, cognitive, role, and social functioning of gynecologic cancer patients. Age, treatment modalities, and symptoms such as pain, dyspnea, and constipation emerge as critical determinants of physical function limitations. Emotional and cognitive functioning are notably affected by symptoms like pain and appetite loss, as well as socioeconomic challenges such as financial impairment. Role and social functioning are influenced by employment status, disease stage, and treatment type, with chemotherapy associated with substantial limitations. These findings highlight the need for comprehensive, multidisciplinary approaches to address the diverse challenges faced by gynecologic cancer patients, aiming to enhance their overall quality of life.

10. RECOMMENDATION

For Researchers

Further studies need to be conducted with increased sample size and with a non-cross sectional method of study design to have a deeper understanding of the factors that directly affect the quality of life of patients with gynecologic cancers.

For Administrators and policy makers

I forward the following recommendations for administrators and policy makers:

Prioritize the development and implementation of effective pain management protocols within healthcare settings to improve both physical and emotional functioning of patients. This can involve training healthcare providers in advanced pain management techniques and ensuring access to necessary medications and therapies.

Establish nutritional support programs for cancer patients, emphasizing the importance of maintaining a balanced diet to improve emotional and physical health. This could include providing nutritional counseling and access to nutrient-rich foods.

Multidisciplinary Care Approach: Establish a multidisciplinary approach in healthcare settings, incorporating physical therapists, nutritionists, psychologists, and social workers to address the diverse needs of cancer patients comprehensively.

Continually review and improve existing chemotherapy protocols to minimize adverse effects.

Financial Assistance Programs: Implementing financial support programs can alleviate the economic burden on patients, thereby reducing stress and improving cognitive and social functioning.

For Clinicians

Clinicians should screen individual patients for their quality of life before start of any treatment; they should treat symptoms like pain optimally, provide psychological support and use alternative chemotherapeutic drugs with lesser side effects and toxicities. Addressing appetite loss and ensuring proper nutrition can help stabilize emotional health.

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ANNEX

Annex 1. Participant Information Sheet, English Version

Good morning/afternoon. My name is_____and I am from_____.
I am a member of a data collector team on behalf of the study conducted by, Dr Walelign Kindie who is a gynecologic oncology fellow in Bihar Dar University, College of Medicine and Health Science, Department obstetrics and gynecology to assist the investigator Dr Walelign Kindie to

obtain data for the investigation on “health related quality of life among gynecologic cancer patients at government hospitals in Bahirdar; Ethiopia”

General information

Title of the project: Health related quality of life among gynecologic cancer patients at government hospitals in Bahirdar; Ethiopia, 2024

Study Design: - institution based cross sectional study

Principal Investigator: **Dr Walelign Kindie**
Supervisor:- ----------

Purpose: The purpose of this research is to assess the health related quality of life and associated factors among gynecologic cancer patients at government hospital in Bahirdar, Ethiopia.

Procedure and participation: The method of this research is an institution based cross sectional study design. The expected duration of the study participant for one- time contact with the interviewer will not be more than 25 minutes. You will be asked to participate in this research since the truthful information which you will provide is important for the understanding of the proposed research project. However, your particular participation is affirmed by the procedure of probability sampling technique which provides an equal chance of selection.

Confidentiality:
The data collector will employ codes rather than names during the data collecting period in order to ensure secure safeguards of the confidentiality of research data. Except for the lead investigator and the supervisor, for the purposes of data checking and cleaning, the original data will be kept locked in cabinets until the data analysis is completed. It is unethical to utilize participants' information for any reason other than those for which they have given their consent. Your personal qualities or privacy are not at risk from the disclosure of the information you supply. The original data questionnaire will be burned in a secure facility after the research defense and final work are authorized by the Bahirdar University senate.

Benefit: The study does not provide immediate financial advantages to the research participants as a whole or as an individual. However, the findings of this study will aid the concerned organizations and policymakers in the consideration of incorporation of HRQoL assessment in treatment guidelines.

Risk: The research subjects are not subjected to any inhumane treatment, bodily damage, social prejudice, psychological distress, or financial loss.

Inducement, incentive, and compensation: The study will not involve any enticement or compulsion, and there are no risks involved that would require payment.

Freedom to withdraw: If you decide to take part in the study, you have the complete freedom to stop at any time without facing any consequences. Nobody will demand or ask you to give a justification for your withdrawal.

Person to contact: Before and during the research project, the participant has the opportunity to inquire about any details that are unclear regarding the context and substance of the study. You can get in touch with the lead researcher and the supervisor of the data collector. The Bahir Dar University College of Medicine and Health Sciences Ethical Review Approval Committee had also reviewed and approved this research. You can get in touch with the following people if you want further details about this research project.

1. Bihar Dar University College of Medicine and health sciences Office phone: +251----------

2. Principal investigator name: Dr Walelign Kindie

   Tell: 0938883386

3. Advisors name& Address

3.1. Dr Eyaya Misgan(Associate professor of gynecology and obstetrics & gynecologic oncologist)

Tell: 0913093115

3.2. Dr Muluken Azage. (Associate professor of water and public health)

Tell: 0911364097

Annex 2. Informed consent agreement form, English version

Title of the thesis project: Health related quality of life among gynecologic cancer patients at government hospitals in Bahirdar; Ethiopia, 2024

I am aware that this research undertaking is a postgraduate subspecialty research project which is fully supported and coordinated by Bahir Dar University and the designated principal investigator is Dr Walelign Kindie.

I have been also fully informed in the language I understood and about the research project objectives. I have been informed that all the information I shall provide to the interviewer will be kept confidential. I understood that research has no risk and no

compensation. I also know that I have the right to withhold information, skip questions to answer or to withdraw from the study at any time. I have been informed that nobody will imposeon me to explain the reason for withdrawal. It is also clear that there will be no effect at all in my health benefit or other administrative effects that I get from the district. I have been assured of the right to ask information that is not clear about the research before and/or during the research work by contacting:

1. Principal investigator name and address:

   Dr. Walelign Kindie

2. Supervisor name and address: _____

I have read this form, or it has been read to me in the language I comprehend, and I understood the condition stated above; therefore, I am willing and confirm my participation by signing this consent form.

Sign:

Name of interviewer_____Signature_____Date _____

Annex 3: Techniqual summary of how to score EORTQLQ-C30

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 (RS).

In practical terms, if items I_1, I_2, ... I_n are included in a scale, the procedure is as follows:

Raw score (RS)

Calculate the raw score: $RS = (I_1 + I_2 + \ldots + I_n)/n$

2. Use a linear transformation to standardize the raw score, so that scores range from 0 to 100.

Linear transformation

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

Linear transformation

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

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

Symptom scales / items: S = {(RS-1)/Range} x100

Global health status / QoL: S = {(RS-1)/Range} x100

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, and the initial yes/no items on the earlier versions of the QLQ-C30 which have range = 1

Annex 4: English version of the EORTQLQ-C30

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:

Your birthdate (Day, Month, Year):

Today's date (Day, Month, Year):

---

1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

2. Do you have any trouble taking a long walk? 1 2 3 4

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

3. Do you have any trouble taking a short walk outside of the house? 1 2 3 4

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

4. Do you need to stay in bed or a chair during the day?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

5. Do you need help with eating, dressing, washing yourself or using the toilet?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

During the past week:

6. Were you limited in doing either your work or other daily activities?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

7. Were you limited in pursuing your hobbies or other leisure time activities?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

8. Were you short of breath? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

9. Have you had pain? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

10. Did you need to rest? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

11. Have you had trouble sleeping?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

12. Have you felt weak? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

13. Have you lacked appetite? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

14. Have you felt nauseated? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

15. Have you vomited? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

16. Have you been constipated? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

During the past week:

17. Have you had diarrhea? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

18. Were you tired? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

19. Did pain interfere with your daily activities?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

21. Did you feel tense? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

22. Did you worry? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

23. Did you feel irritable? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

24. Did you feel depressed? Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

25. Have you had difficulty remembering things?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

26. Has your physical condition or medical treatment interfered with your family life?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

27. Has your physical condition or medical treatment interfered with your social activities?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

28. Has your physical condition or medical treatment caused you financial difficulties?

Not at All (1) A Little (2) Quite a Bit (3) Very Much (4)

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

29. How would you rate your overall health during the past week?

1 2 3 4 5 6 7

Very poor Excellent

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

1 2 3 4 5 6 7

Very poor Excellent

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Annex 5: Amharic version of EORTQLQ-C30

EORTC QLQ-C30 (አትም 3)

እርስዎንና ጤንነትዎን በተመለከተ የተወሰኑ ነገሮችን ለማወቅ እንፈልጋለን። እባክዎትን የሚከተሉትን ጥያቄዎች በሙሉ እርስዎ ትክክለኛ ነውብለውያመኑበትን በሚከበብ ይመልሱ። «ትክክለኛ» መልስ ወይም «የተሳሳተ» መልስ የሚባል የለም። የሚሰጡት ሚጃ ሁሉ ምስጢራዊነቱ በደንብ የተጠበቀ ይሆናል።

እባክዎን የእርስዎን የአባትዎንና የአያትዎን የስምመጀመሪያ ፊደል ይጻፉ፡-

የተወለዱበት ዕለት (ቀን፣ ወር፣ ዓም)፡-

የዛሬውዕለት (ቀን ፣ ወር፣ ዓም)፡-

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1. እንደ ከባድ ዘንቢል ወይምሻንጣመሸከምየ መሳሰሉ ጉልበት የሚጠይቁ እንቅስቃሴዎችን ለመድረግ ችግር አለብዎት?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

2. ረዥም የእግር ጉዞ ለማድረግ ችግር አለብዎ?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

3. ከቤትዎ ውጭ ያሉ የእግር ጉዞ ለማድረግ ችግር አለብዎ?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

4. በህመምዎ የተነሳ በቀን አልጋ ላይ ወይም ወንበር ላይ ሆነ ውረዘ ምላለ ሰዓት ያሳልፋሉ?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

5. ሲማ ቡ፣ ሲለብሱ፣ ሲታጠቡ ወይም ሽንት ቤት ሲጠቀሙ እገ ዛ ያስፈልግዎታል?

ባለፈውሳምንት ወስጥ፦

6. ስራዎትን ወይንም የዕለት ተለት እንቅስቃሴዎትን ለማከናወን ተገ ደብውነበር?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

7. በትርፍ ጊዜ የሚከናወኑ ስራዎችን ወይንም ሌሎች የመዝናኛ ጊዜዎችን ለማከለፍ ገ ደቦዎት ነበር?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

8. ሲተነ ፍሱ የትንፋሽ ማጠር አጋጥሞት ነበር?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

9. የህመምስሜት ነበረብዎ?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

10. ከወትሮውየ ተለየ ዕረፍት አስፈልጎዎት ነበር?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

11. የዕንቅልፍ ችግር ነበረብዎ?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

12. አቅምያንስዎት ነበር?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

13. የምግብ ፍላጎትዎ ቀንሷል?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

14. የማቅለሽለሽ ስሜት ነበረብዎ?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

15. አስመልሶዎት ነበር?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

16. የሰገ ራ ድርቀት ነበረብዎ? በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

ባለፈውሳምንት ወስጥ፦

17. ተቅማጥ ነበረብዎ?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

18. የድካምስሜት ነበረዎ?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

19. ህመምየዕለት ተዕለት እንቅስቃሴዎትን ያወክብዎ ነበር?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

20. አንድአንድ ነገሮችን ትኩረት ሰጥተውለማከራት ያወክዎት ነበር (ለምሳሌ፤ ጋዜጣለማንበብ፣ ራዲዮ ለማዳመጥ)?

በጭራሽ (1) በትንሹ (2) በማኩ (3) በጣም በብዛት (4)

21. የወጥረት ስሜት ነበረብዎ?

በጫራሽ (1) በትንሹ (2) በማጡ (3) በጣም በብዛት (4)

22. የሜጨቅ ስሜት ነበረብዎ?

በጫራሽ (1) በትንሹ (2) በማጡ (3) በጣም በብዛት (4)

23. የማ ጫ ጭስሜት ነበረብዎ?

በጫራሽ (1) በትንሹ (2) በማጡ (3) በጣም በብዛት (4)

24. የመደበር ስሜት ነበረብዎ?

በጫራሽ (1) በትንሹ (2) በማጡ (3) በጣም በብዛት (4)

25. ነገሮችን የማስታወስ ችግር ነበረብዎ? በጫራሽ (1) በትንሹ (2) በማጡ (3) በጣም በብዛት (4)

26. አካላዊ ሁኔታዎ ወይምየ ማከታተሉት ህክምና <u>በቤተሰባዊ</u> ህይወትዎ ላይ ያሳደረው ተጽዕኖ ነበር? በጫራሽ (1) በትንሹ (2) በማጡ (3) በጣም በብዛት (4)

27. የጠፍዎ ሁኔታ ወይምየ ማከታተሉት ህክምና <u>በማህበራዊ</u> ሕይወትዎ በሚደርጉት እንቅስቃሴዎ ላይ ያሳደረውተጽዕኖ ነበር?

በጫራሽ (1) በትንሹ (2) በማጡ (3) በጣም በብዛት (4)

28. የጠፍዎ ሁኔታ ወይምየ ማከታተሉት ህክምና ገንዘብ እንዲያጥርዎ /እንዲቸግርዎ/ አድርጓል?

በጫራሽ (1) በትንሹ (2) በማጡ (3) በጣም በብዛት (4)

ለማከተሉት ጥያቄዎች ከ 1-7 ካሉት ቁጥሮች ወስጥ እርስዎን በደንብ የሚገልጽዎን አንዱን ቁጥር ያክብቡ

29.በአጠቃላይ ባለፈውሳምንት የነበረዎን <u>የጤንነት</u> ሁኔታ እንዴት ይመዘኑታል?

1 2 3 4 5 6 7

በጣም መጥፎ እጅግ በጣም ጥሩ

30.በአጠቃላይ ባለፈውሳምንት የነበረዎን <u>የኑሮ ሁኔታ ጥራት</u> እንዴት ይመዘኑታል?

1 2 3 4 5 6 7

በጣም መጥፎ እጅግ በጣም ጥሩ

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Annex 6: English questionnaire

Participant ID No_____Kebele_____

Interviewer name_____Date of interview_____

Starting time_____ ending time_____

Part I: - SOCIOECONOMIC and DEMOGRAPHIC DATA

Sr. no	Questions	Response	Remark
1.	Age	_____year	
2.	Marital status	1. Single 2. married 3. divorced 4. widowed	
3.	Religion	1. orthodox 2. Muslim 3. Protestant 4. Others----------	
4	Educational status	1. Illiterate 2. Primary school 3. Secondary school 4. Higher education	
5.	Occupation	1. Farmer 2. Government employed 3. Self-employed 4. Student 5. Unemployed 6. Housewife	
6.	Residence	1. Urban 2. Rural	
7	Monthly income (ETB)	_____	
8.	Medical fee	1. Insured 2. Paying	
Part II: obstetrics and gynecologic data			
9.	Parity		
10.	Number of alive children		
11.	Are you on postmenopausal	1. Yes 2. No	
12.	If your answer to Q11 is yes, how many years since menopause?		

Part III: clinical data			
13.	Type of cancer		
14.	Duration since diagnosis		
15.	Stage of cancer		
16.	Type of treatment		
17.	Number of chemotherapy sessions if the answer to Q16 includes chemotherapy		
18.	Comorbidities		
Part IV: quality of life data			
See ANNEX 4- the English version of EQRTQLQ-C30 version 3.			