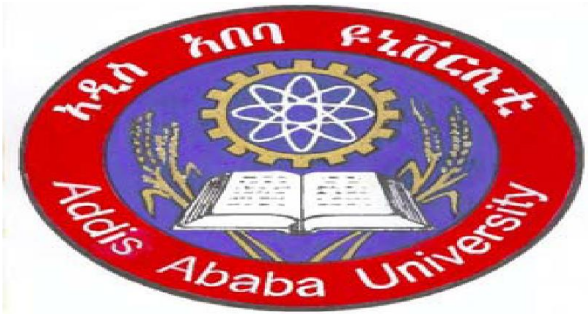

VALIDITY OF EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER QUALITY OF LIFE TOOLS IN COLORECTAL AND OESOPHAGOGASTRIC CANCER PATIENTS IN ETHIOPIA, 2020

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Examiners' Approval Sheet

We, the undersigned, members of the Board of Examiners of the final open defense by Lidya Genene Abebe, have read and evaluated her thesis entitled *"Validity of the European organization for research and treatment of cancer quality of life tools in colorectal and oesophagogastric cancer patients in Ethiopia, 2020."* This is to verify that the thesis has been accepted in partial fulfillment of the requirements for the masters of public health degree in "Epidemiology and Biostatistics"

Name of internal examiner:

Signature _____

Date:

Name of external examiner:

Date

Signature _____

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List of acronyms and abbreviations

CR-29	European Organization for Research and Treatment of cancer tool for Colorectal cancer
C-30	European Organization for Research and Treatment of cancer tool
EORTC	European Organization for Research and Treatment of cancer
EORTC- QLQ-C30	European Organization for Research and Treatment of Cancer Quality of Life questionnaire for cancer patients
EORTC QLQ-C29	European Organization for Research and Treatment of Cancer Quality of Life questionnaire for colorectal cancer patients
EORTC QLQ-OG25	European Organization for Research and Treatment of Cancer Quality of Life questionnaire for esophagogastric cancer patients
EQ-5D	Euro Quality of Life – 5 dimension questionnaires
FACIT	Functional Assessment of Chronic Illness Therapy
GLOBOCAN	Global organization board of cancer association network
HRQoL	Health related Quality of Life
NCDs	Non communicable diseases
OG-25	European Organization for Research and Treatment of cancer tool for Oesophagogastric cancer
PCA	principal component analysis
QLQ CR	Quality of life tool in colorectal cancer patients
QLQ OG	Quality of life tool in oesophagogastric cancer patients
QOL	Quality of Life
RS	Raw score
RSCL	the Rotterdam Symptom Checklist
SDS	Symptom Distress Scale
WHO	world health organization

Abstract

Background- Gastro intestinal cancers and their treatments have detrimental effect on patients' Quality of Life. The European Organization for Research and Treatment of Cancer (EORTC) tools which had been developed to assess quality of life among colorectal and oesophagogastric cancers patients were validated and used in different countries. However, the tools have not been translated into local language nor validated in Ethiopian context. Therefore, this study aimed to validate EORTC quality of life tools in Ethiopian colorectal and oesophagogastric cancer patients.

Methods: Institution based cross-sectional study was done at Tikur Anbessa Specialized Hospital from March to May, 2020. Based on the recommendations given for multi trait scale analysis, 158 colorectal and 158 oesophagogastric cancer patients at the time of data collection period were consecutively included. SPSS version 21 was used for the analysis. The validity and reliability were evaluated in terms of acceptability, internal consistency, face validity, convergent, divergent, clinical validity and unidimensionality of the tools.

Result: Among the participants 52.2% were male. The median age of the participants was 48 (IQR =17.75). The alpha values ranged from 0.47- 0.91 and 0.39 - 0.7 for colorectal and oesophagogastric tools, respectively. Multi trait scale analysis showed that all items correlations within their scales were greater than 0.4 except for blood and mucus in stool, dysphagia, eating and odynophagia scales. The value of correlation coefficients between all items and their own domain were higher than other domains except for eating, odynophagia, dysphagia, anxiety, and blood and mucus in stool scales. The correlation between the core questionnaire and colorectal tool ranged from -0.46– 0.57. Similarly, oesophagogastric and the core questionnaire correlation extended from -0.65-0.62. The tools also discriminated among clinically distinct groups.

Conclusion: Even though the tools' clinical validity was supported, the convergent and divergent validity of eating, odynophagia, dysphagia, anxiety, and blood and mucus in stool scales were not supported. Thus, the finding suggested doing confirmatory factor analysis.

1. Introduction

1.1 Background

In 2016, non-communicable diseases (NCDs) were responsible for 41 million deaths worldwide. They accounted for 71 % of all deaths, and the burden was high in low and middle income countries. From the NCDs, cancer was one of the major contributors of NCDs death (1). In 2018, Global organization board of cancer association network (GLOBOCAN) estimated that there are 18.1 million new cancer cases and 9.6 million cancer deaths worldwide (2). From cancer cases, colorectal and oesophagogastric were the most commonly diagnosed cancer cases. Colorectal cancer ranked third, gastric ranked fifth and esophageal ranked seventh.

Similarly, based on 2015 Addis Ababa cancer registry report; colorectal cancer was the leading cancer case in male and it ranked fourth in female in Ethiopia (3). Likewise, a study conducted in Addis Ababa showed that gastrointestinal cancer was the fifth most frequently diagnosed cancer case (4).

Cancer treatments have adverse effect and toxicity which affect quality of life (5). Moreover, Gastrointestinal cancer patients have suffered from problems that emerged as a consequence of the disease and the treatments which negatively affect their quality of life (6). Thus, it is recommended to collect information on health related quality of life which is later assumed to guide decision making in treatment choice (7).

World Health Organization (WHO) defines Quality of Life (QoL) 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" (8).

Currently, different tools are available to assess quality of life among cancer patients. From them, EORTC tool has been recommended to be used when the aim of the study is to assess disease specific symptoms (9,10).

This EORTC core questionnaire comprises nine scales. From the scales, five are functional scales, three symptom scales and a global health scale. The functional scales contain physical, role, cognitive, emotional, and social scales. And the symptom scales include fatigue, pain, and nausea and vomiting. Beside the scales, it also has six single items to assess additional symptoms and perceived financial impact of the disease and treatment (11). Additionally, to complement this questionnaire different disease specific modules have been developed. Colorectal and oesophagogastric cancer modules are among these tools; they have been validated in different studies such as in Mexican, Spanish, Korean, Ireland, Taiwan, Chinese and Polish (12–18).

1.2 Statement of the problem

Worldwide, cancer is the second leading cause of death next to cardiovascular diseases (1). Furthermore, colorectal and oesophagogastric cancer cases are among the most widely diagnosed cancer cases and major contributor of cancer death(2). On top of that, a cancer and its treatment have been known to have psychological effect. It has also been known to affect patients' emotion which, in turn, have an effect on patients' quality of life (19,20). Besides, treatments for gastrointestinal cancer and the disease themselves have been known to have a negative impact on quality of life of the patients (6,21).

According to a study conducted in China, the Health Related Quality of Life (HRQoL) of colorectal cancer patients was significantly lower than the general public (22). Another study conducted in China also found that esophageal cancer patients had worse HRQoL after taking treatments (23). Similarly, a study conducted in Dutch among gastric cancer patients showed that patients who underwent gastrectomy had a worse score on most functional and symptom scales (24).

Since quality of life has been known to be a predictor for survival in cancer patients (25–28), cancer treatments have started incorporating quality of life as one end point (29). In addition to this, the rising of colorectal and gastrointestinal cancers in Sub-Saharan Africa (30,31) along with low QoL of heterogeneous cancer patients in Ethiopia(32) made QoL a major area to focus on. Accordingly, the Ethiopian Federal Ministry of Health has put a strategy to assess and treat distressing symptoms in cancer patients(33). However, the health related QoL of colorectal and esophagogastric cancer patients have not been widely studied in Ethiopia. This might be due to the unavailability of validated tools.

Having sensitive and validated tool to assess QoL is very crucial. Hence, EORTC groups developed cancer specific QoL modules for colorectal and esophagogastric cancers(34,35). However, the tools should not be used as they are in other countries. As mentioned on the original finding, further tests in different countries are needed to address cross-cultural differences. Not only this, but also the cultural difference between Ethiopia and the original studies as well as the areas where the tools have been validated (12–18) makes it difficult to adopt and use the tools without doing validation test.

So far, EORTC Quality of Life core questionnaire (EORTC QLQ -30) and cervical module have been checked for their validity in Ethiopia (36,37). Thus, one might consider the transferability of these studies' findings to other tools. Nonetheless, due to different nature of the diseases and different effect on HRQoL, considering transferability might not be appropriate. In addition, none of those studies in Ethiopia has tried to see the unidimensionality of the tools. What is more is that, whenever the tools are translated to other language, it is recommended to do validation test (38). As far as we know, EORTC tools for colorectal and esophagogastric cancer patients were not validated in Ethiopia. Hence, the present study intended to assess the validity of the tools in Ethiopian colorectal and esophagogastric cancer patients.

1.3 Significance of the study

The finding of this study may help researchers to use validated tool to measure the HRQoL of colorectal, esophageal, and gastric cancer patients in different studies of similar setting. This study may contribute to the body of knowledge on the tools validity across different culture and country. Having validated tools may also help colorectal, esophageal, and gastric cancer patients to get comprehensive care and to communicate problems to health care providers. Furthermore, these tools may help to collect information that can be communicated to future patients to enable them to anticipate and understand the consequences of their illness. Additionally, having validated tool may help to find out hidden problems which make patients worry. Moreover, these tools may help physicians to consider patients' perspective while deciding on treatment option.

2. Literature review

2.1 Introduction

Literature has been searched using Pubmed, Google scholar and Google search engines. Health related quality of life, cancer incidence, colorectal cancer, esophagogastric cancer, validity of European Organization for Research and Treatment of Cancer Quality of Life questionnaire for colorectal and esophagogastric cancer patients (EORTC QLQ C-29 and EORTC QLQ OG-25)have been used as key words to search the literature. From the articles obtained, a limited number of published and free articles which were written in English and were found to be very relevant to this study have been selected for review. The first section of this literature review focuses on the magnitude of colorectal, esophageal and gastric cancers. The second section of this literature review deals with HRQoL of colorectal, esophageal and gastric cancer patients. The third section focuses on EORTC QLQ-C29 and EORTC QLQ-OG25 tools. The fourth section deals with Validity of EORTC QLQ OG25 tool. And the last section of this literature review focuses on Validity of EORTC QLQ-CR29 tool.

2.2 The magnitude of Colorectal, Esophageal and Gastric cancer

As stated in GLOBOCAN 2018 report, colorectal cancer was estimated to be responsible for More than 1.8 million new cancer cases and 881,000 deaths (2). Worldwide, the incidence of colorectal cancer is higher in developed countries; but the mortality is higher in less developed countries. In 2012, colorectal cancer incidence was 17.2 per 100,000. This incidence is expected to rise with estimated incidence of 2,440,905 and estimated mortality rate of 1,283,206 by the year 2035 (39). Colorectal cancer was the fifth most frequently diagnosed cancer case in sub-Saharan Africa (40). The incidence and mortality rate of this disease is increasing in low- income and middle income countries (41). As per a study conducted in Tikur Anbessa Specialized Hospital, colorectal cancer was the third most commonly diagnosed cancer case in the age group between 15-29 (42).

In 2018, gastric cancer accounted for 1,000,000 new cancer cases and 783,000 deaths worldwide. Esophageal cancer was responsible for 572,000 new cases and 509,000 deaths (2). Based on a study in 2012, there were 27,500 new esophageal cancer cases and 25,200 deaths in Africa (43).

More than 70 % of the cases occurred in Sub-Saharan Africa, and it was slightly more common in male than female (40). In Sub-Saharan countries, esophageal cancer was one of the top five cancer cases in people aged 60 and over (44). Similarly, gastric cancer was the fifth and esophageal was the sixth most commonly diagnosed cancer case in the age group between 15-49 in Tikur Anbessa Specilized Hospital (42).

In general, cancer as well as treatments which target on survival have a significant effect on patients' quality of life (5). Hence, comprehensive cancer treatment has prompted an interest toward the concept of quality of life.

2.3 Health related quality of life of patients with Gastric, Esophageal and Colorectal cancer patients

Chronic diseases are determinant factors for health related quality of life (45–47). And cancer is one of the chronic diseases which affect quality of life (48). These days, different researches are being conducted to assess HRQoL among cancer patients. According to a cross sectional study in Trinidad and Tobago, the mean values for global QoL and function scales were below 75 (49). Similarly, a study conducted in Ethiopia showed that the mean value for QoL of cancer patients was 52.7 (32). Furthermore, gastrointestinal cancer and its treatments have been known to have a negative effect on patients' quality of life (6).

Based on a study conducted among Slovenian patients, colorectal cancer patients had significantly lower physical, role, cognitive and social functioning scores. Moreover, they had higher frequency of constipation, diarrhea and financial difficulties. However, this study didn't find significant global health score difference between patients and the general population. This might be due to low response rate or the non-response group global health score might be different from those participated in the study (50).

In line with the above finding, a study conducted in Germany depicted that colorectal cancer patients scored more severe limitations for emotional, social functioning, and symptom subscales namely: fatigue, dyspnea, insomnia, constipation, diarrhea, and financial difficulties (51). However, the overall QoL and physical functioning of patients and the general population were comparable. This might be due to the fact that respondents had better education and tended to

live with a spouse than the non-respondents (51). Like the above studies, a systematic review found that long-term colorectal cancer survivors had worse physical functioning, long-lasting symptoms, and depression scores when compared to the general population (52).

Another study conducted in china showed that the HRQoL of esophageal cancer patients was impaired in a daily life after treatment(23). Similarly, a study conducted in Netherlands found that most of the HRQoL scores of the esophageal cancer patients were worse than that of the esophageal cancer survivor. The study showed that the survivors' HRQoL scores were worse than the general population(53).

Likewise, a systematic review on gastric cancer patients found a decline in HRQoL of patients after 1 month of surgery, but it returned to at least a pre-operative level by 1 year(54). Another study conducted on 465 Korean gastric cancer patients stated that fatigue, digestive symptoms, body image, disturbance, and cognitive functioning persisted up to 12 months after surgery (55).

2.4 EORTC QLQ-OG25 and EORTC QLQ-C29 tools

To assess quality of life among cancer patients, different sensitive, reliable and validated tools were developed. The most frequently used tools are EORTC QLQ-C30, the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System, the Rotterdam Symptom Checklist (RSCL), and the Symptom Distress Scale (SDS) (56). From them, EORTC QLQ-30 and its disease specific modules are the most widely used measures. Even though separate specific modules for gastric and esophagheal cancer are available, it has not been well known which module is best to assess quality of life in esophagogastric junction cancer. For this reason, the EORTC developed a validated tool which helps to measure quality of life in gastric, esophageal and esophagogastric junction (35)**.**

EORTC QLQ OG25- is a 25-item module. It was developed to increase the sensitivity and specificity QLQ-C30 tool. This module has six symptom scales and 10 single-item symptoms. These scales are eating restrictions, reflux, dysphagia, odynophagia, discomfort and pain, and anxiety. Like the original tool, lower scores show less symptomatic problems. (35).

EORTC QLQ-CR29- is a 29 items module and it was developed to complement the QLQ-30 questionnaire. It comprises four scales assessing urinary frequency, blood or mucus in the stools, stool frequency and body image. These scales are generally classified as functional and symptom scales. In addition, it has 19 single items to assess other problems patients face(34).

2.5 Validity of EORTC QLQ-CR29 tool

In a Korean study conducted to evaluate the validity of EORTC colorectal tool, 123 colorectal cancer patients were included (15). The study depicted that the time for completion of the questionnaire was less than 20 minutes. It found the tool to be reliable with Cronbach's α coefficients ranging from 0.70–0.87. Even though the study did not fulfill the minimum sample size for multi- trait analysis(57), all items correlation within their scales were greater than 0.4. On the other hand, the value of correlation coefficients between all items and their own domain were higher than other domains. This proved that the tool fulfilled the criteria for convergent and divergent validity.

The correlation between the colorectal tool (CR-29) and core questionnaire (C-30) ranged from -0.63-0.62. The highest correlation was noted between stoma care problem and cognitive function. Body image showed correlations above 0.4 with physical, role, cognitive, emotional, social, and pain domains. Similarly, anxiety had correlations of above 0.4 with physical, emotional, role and pain scales and item. In addition, Flatulence, faecal incontinence, stool frequency, abdominal pain, taste, and weight had correlation above 0.4 with fatigue item. Most of the correlations between them were below 0.4. This depicted that the two questionnaires are meant to measure different aspects. Known-groups comparisons were conducted to colon and rectal cancer patients, and patients with stoma and those without stoma. Body image, sore skin, anxiety, sore skin and embarrassment differentiated patients with stoma and without stoma.

In Spanish version study, 84 rectal cancer patients were included, which is below the recommended sample size for multi-trait analysis (14). There were 72 missing items (2.9%), mainly concentrated on sexuality items. This finding is similar to the original study (34) in which there was 2.3% missing. This study didn't mention on how missing items were handled. Unlike the Korean study (15), all items didn't have Cronbach's α coefficients value greater than 0.7. They ranged from 0.27 -0.7. This study employed multi-trait analysis and found the scales to

fulfill the criteria for convergent and divergent validity except for item 38 and 39 (blood and mucus in stool) which was 0.27. Further, known group comparison was done based on age, performance status and presence of stoma. And stool frequency scale found to discriminate patients with stoma and without stoma. The correlation test between the core questionnaire and CR-29 revealed correlations of above 0.4 between body image and social and emotional functioning, abdominal pain and pain, faecal incontinence and diarrhea, and buttock pain and constipation.

Another study conducted in China included 356 patients and found 3.4% missing items related to sexual problem (13). This is somewhat higher than the original study(34). This might be due to cultural difference of Asian and Western countries. This study only had Cronbach's α of greater than 0.7 for body image scale. Findings from convergent and divergent validity showed that values of correlation coefficients between items and their own domain were higher than other domains. In addition, the known group comparison found difference between groups based on stoma and physical functioning. Body image, urinary incontinence, buttock pain, dry mouth, taste, anxiety, weight, flatulence, faecal incontinence, sore skin, and embarrassment showed differences between patients with stoma and without stoma. Similarly, except from urinary incontinence, body image, abdominal pain, dry mouth and stoma care; all other scales and items differentiated patients with better and worse physical functioning. The core questionnaire and the tool had correlations of above 0.4 with blood and mucus in stool, stool frequency, abdominal pain, taste, anxiety, and sore skin.

Similarly, a study in Taiwan found the tools to have Cronbach's α of greater than 0.7 for all scales. It also found the questionnaire to differentiate groups based on stoma and physical function and patients on active treatment and follow up (58). Sexual function in female and urinary frequency differentiated patients with better and worse physical functioning. Similarly, only blood and mucus in stool scale discriminated patients with stoma and without stoma.

A study conducted in Dutch included 236 participants, employed exploratory factor analysis and found 7 factors and fewer single items (59). The correlations between CR-29 subscales and the C-30 subscales were found to be below 0.40, except for body image, which correlated with social functioning. Similar to the original study (34), in this study the reliability in the blood and mucus

scale was below 0.7. Known-groups comparisons were conducted to compare older and younger patients, patients with and without a stoma, and patients treated with curative and palliative intent. Like the original tool, urinary incontinence and body image were able to distinguish patients with stoma and those without stoma. In addition, buttock pain and anxiety items also differentiated the groups. However, fewer differences were found between these groups when compared to the original study. For treatment intent, blood and mucus in stool, buttock pain, hair loss, trouble with taste, faecal incontinence, and stool frequency discriminated between palliative and curative intent groups. The correlations test between core questionnaire and the tool found that body image had a correlation above 0.4 with social functioning otherwise all correlations were less than 0.4

To sum it up, these six studies found the tools to be reliable and to have convergent and divergent validity (which means the studies support the original tools item and scale classification). Moreover, they also showed the clinical validity of the tool. Besides, in all studies for almost all items correlation between most of CR-29 items and C-30 items was below 0.4. And these depicted that the tools are meant to measure different aspects. Even though there were some missing in sexuality items in Spanish, Chinese, and the original studies; all of these studies found more than 80% response rate. And this showed the acceptability of the questionnaires. There were different findings on the reliability of blood and mucus in the stool items. Correlation test of the core questionnaire and CR tool showed correlations of above 0.4 for body image, anxiety and embarrassment with emotional function.

2.6 Validity of EORTC QLQ OG25 tool

Different studies found oesophagogastric tool (OG-25) to be reliable and the time for completion of the questionnaire to be less than 30 minutes. The original OG-25 tool validity study administered on 300 patients found the tool to be reliable with Chronbach alpha ranging from 0.67–0.87 (35). Similarly, studies conducted in Polish and Mexican esophagogastric cancer patients administered on 93 and 163 patients, respectively, found the questionnaires to have a Chronbach alpha value of greater than 0.7 (12,16). In Mexican and Polish studies, patients filled the questionnaire with in less than 30 minutes and 20 minutes, respectively.

Studies presented higher correlation for item correlation with in scale than with other scale. Even though the Polish study didn't fulfill the minimum sample size for multi trait analysis(57), item correlation with in scale ranges from 0.73-0.98 and item correlation with other scale ranges from -0.04-0.75 (16). Similarly, in the original study item correlation with in scale ranges from 0.44-0.78; item correlation with other scale ranges from 0.03-0.64 (35). Likewise, the Mexican study has item correlation with in scale ranging from 0.3-0.66 and item correlation with other scale ranges from 0.01-0.65 (12).

Though the tool has been found to differentiate clinically distinct groups of patients, different studies have used different groupings for assessing its clinical validity. The original study groups patients based on tumor site and disease stage (35). The Mexican and the Polish studies used treatment group for comparison (palliative and curative) (12,16). The Mexican study (12) found significant difference based on treatment group. But in Polish study (16)only trouble with saliva distinguished the group. The reason might be by the time this symptom develops, the disease is usually at incurable stage(60). Moreover, in Polish study the sample size was small and this might underestimate the difference based on treatment groups.

According to the original, Mexican, and Polish studies(12,16,35), there was overlap between the C-30 and OG-25, and there was also correlation less than 0.4 which indicated that the two questionnaires assess different aspects. The original study (35) also found correlation between the odynophagia scale and C-30 pain scale. Furthermore, the Polish study (16) also found above 0.6 correlations between the nausea and vomiting scale of the C-30 and the dysphagia and eating restriction scales of the OG-25. And the Mexican study(12) found correlation values greater than 0.4 for nausea and vomiting with eating restriction and dysphagea. Global quality had correlations of above 0.4 with all scales except with hair loss and trouble with coughing. Similarly, physical function and pain had correlation above 0.4 with all scales except with hair loss and anxiety scale. In all of the studies, there was overlap between the two questionnaires and there was also week correlation which indicated that the two questionnaires assess different aspects.

Although some items' correlations within their scales and other scales didn't fulfill convergent and divergent validity, all studies suggest that the tool have convergent and divergent validity.

They also convey that the tool is reliable and clinically valid to assess health related quality of life in esophagogastric cancer patients. The correlations between OG-25 and core questionnaire were inconclusive; different studies found different correlation values.

2.7 Conclusion

Though the different studies reviewed above found the CR-29 and OG-25 tools to be valid, these tools need to be validated in other countries with different socio-cultural context. What is more is that, the divergent and convergent validities for mucus and blood scale of CR-29 have remained ambiguous. Apart from that, as it can be seen in the literature, limited studies were found in Africa. As far as we know, these tools have not been validated in Ethiopian colorectal and esophagogastric cancer patients. Therefore, this study intended to examine the validity of these tools.

2.8 Research questions

1. Is the EORTC QLQ-C29 tool valid in Ethiopian colorectal cancer patients?
2. Is the EORTC QLQ OG-25 tool valid in Ethiopian oesophagogastric cancer patients?

3. The research objective

3.1 General Objective

To validate EORTC tools in Ethiopian colorectal and oesophagogastric cancer patients diagnosed in Tikur Anbessa Specialized Hospital, 2020.

3.2 Specific objectives

1. To examine the construct validity of EORTC QLQ-CR29 in Ethiopian colorectal cancer patients diagnosed in Tikur Anbessa Specialized Hospital, 2020
2. To check the clinical validity of EORTC QLQ-CR29 in Ethiopian colorectal cancer patients diagnosed in Tikur Anbessa Specialized Hospital, 2020
3. To evaluate the construct validity of EORTC QLQ-OG25 in Ethiopian oesophagogastric cancer patients in Tikur Anbessa Specialized Hospital, 2020
4. To examine the clinical validity of EORTC QLQ-OG25 in Ethiopian oesophagogastric cancer patients in Tikur Anbessa Specialized Hospital, 2020

4. Methods and Materials

4.1 Study area

The study was conducted at Tikur Anbessa Specialized Hospital which is the largest referral and teaching hospital in Ethiopia. To date, it has been the only radiotherapy center in Ethiopia. In this oncology center, there are two radiotherapy machines, 36 beds in patient and 12 outpatient chemotherapy beds. There are also six clinical oncologists who provide the oncology services (61). This hospital was selected because patients who need cancer treatments are referred to this hospital from all corners of the country. Therefore, it was assumed that patients from this Hospital would be representative of all cancer patients in Ethiopia.

4.2 Study design and period

Institution based cross sectional study was carried out from March to May, 2020.

4.3 Target population

The target population was all colorectal, esophageal and gastric cancer patients in Ethiopia.

4.3.1 Source population

All colorectal, esophageal and gastric cancer patients who were diagnosed and treated at Tikur Anbessa Specialized Hospital were the source population.

4.3.2 Study population

All colorectal, esophageal and gastric cancer patients who were diagnosed and treated in Tikur Anbessa Specialized Hospital from March to May 2020 were the study population.

4.3.3 Study unit

The study unit was 316 colorectal, esophageal and gastric cancer patients diagnosed and treated in the selected hospital and who fulfilled the inclusion criteria.

4.3.4 Inclusion and exclusion criteria

Inclusion criteria

Since Amharic is official language of Ethiopia, this study aimed to assess the validity of Amharic version of EORTC QLQ-C29 and EORTC QLQ OG-25. Therefore, pathologically confirmed colorectal, esophageal and gastric cancer patients who were ≥ 18 years and who could speak Amharic language were eligible to be part of the study.

Exclusion criteria

Patients with known psychiatric disorders were excluded from the study.

4.4 Sample size

The sample size was calculated based on the recommendations given for scaling analysis and principal component analysis (PCA) (57,62). For scaling analysis, sample sizes of greater than 100 is recommended (57). Similarly, for PCA a minimum of 100 sample sizes or five subject per variable are recommended (62). So, a minimum of five subjects per variable was hypothetically considered to be included. Therefore, 158 colorectal and 158 esophagogastric cancer patients were included.

4.5 Sampling procedure

Since Gastro-Intestinal cancers are not prevalent cases, all colorectal and esophagogastric cancer patients attending Tikur Anbessa Specialized Hospital at the time of data collection were consecutively included.

4.6 Data collection Process

Colorectal and esophagogastric tools were adopted and used. The Amharic version of EORTC QLQ C-30 was also used to determine the correlation between this tool and disease specific tools. In addition, a structured questionnaire was used to assess socio demographic and clinical characteristics of participants developed after reviewing literatures. And the data was collected by two nurses who have bachelor's degree and work in oncology centre. Training was given to

the data collectors for three days on how to collect the data focusing on the purpose of the study, contents of the questionnaire, how to approach and get consent from patients by the principal investigator. The principal investigator supervised the data collection process every other day to monitor data collection procedure. Patients were approached in the waiting room while waiting for their turns or after receiving treatment.

4.7 Data quality control

The Validated Amharic version of EORTC QLQ C-30 was used. EORTC QLQ CR-29 and EORTC QLQ OG-25 were translated according to EORTC translation guideline (63). Two native Amharic speakers independently translated the instrument from English to Amharic. These versions were discussed in the research group and a common consensus was reached. After that, two proficient English speakers back translated the Amharic version to English version. Then it was sent to EORTC translation group for reviewing and proofreading. After receiving the comments from EORTC translation group, pre-test was conducted. This pre-test was conducted at Tikur Anbesa Hospital prior to the actual study, and those who were included in pre-test were excluded from the actual study. Based on the recommendation of 10 participants to consider enrolling in a pre-test (63), 10 colorectal and10 esophagogastric cancer patients were included. The pre-test was conducted to identify questions which were confusing, upsetting or containing difficult vocabulary, difficult to answer questions and to identify any other problems that the patients encountered. And, none of the questions was found to be difficult, confusing or upsetting. Once all comments were discussed and incorporated, the translation was finalized, and an approval to use the translated tool was obtained from the EORTC group. Therefore, the tools met the criteria for face validity.

4.8 operational definition

Acceptable the tools- the tools are said to be acceptable if the response rate is more than 80 %, and the average time needed to complete the questionnaire is below 25 minutes(12,15,16).

Overlap of a tool- if all correlation coefficients between a tool scales and items and the EORTC QLQ-C30 scales and items were greater than 0.4, an overlap is considered.

Face validity- is supported if the questions are not confusing, upsetting, and do not contain difficult vocabulary and difficult to answer questions.

Convergent validity- is supported if the item domain correlation is at least 0.40.

Divergent validity- is satisfied if the value of correlation coefficients between the item and its own domain is higher than other domains.

Construct validity- is assumed to be fulfilled if both the scales fulfil both convergent and divergent validity.

Clinical validity- is satisfied if a tool is able to detect differences between groups which are hypothetically assumed to differ.

4.9 Data processing and management

Completeness of the questionnaires was assessed by principal investigator. Data was double entered using Epi info version7 by two data clerks and inconsistencies of the entered data was reconciled by checking the questionnaire. Data was cleaned and coded, then it was exported in to SPSS version 21 for analysis.

4.10 Data analysis

Descriptive statistics was run to determine proportion and frequency for the socio-demographic characteristics and clinical data then it was presented using table. The validity and reliability of the EORTC CR-29 and OG-25 was assessed in terms of acceptability, face validity, internal consistency, convergent validity, divergent validity, and clinical validity. The specific modules'

correlation with the original tool was checked to see whether the tools are meant to measure different things. Furthermore, the undimensionality of the scales was examined.

The acceptability of the EORTC-CR-29 and OG-25 was assessed in term of response rate, missing data and time needed to complete the questionnaire. The reliability was assessed by measuring the internal consistency of EORTC-CR-29 and OG-25 using Cronbach's α coefficient. A value of 0.70 or greater was considered as adequate (57).

Principal Component Analysis (PCA) was done to check the unidimensionality(64). Before conducting PCA, the assumptions were checked. The Kaiser-Meyer-Olkin measure of sampling adequacy and Bartlett's test of sphericity ($p < 0.05$) were checked. The unidmensionality of scales or a tool was evidenced if the first component explained more than 20 % of the variance(65). To decide the number of components in the tools, the criteria used was based on Eigen value one, parallel analysis and the scree plot. Components with Eigen values above a sharp break of the slope of the plotted line was retained (66). Since EORTC CR-29 tool has more single items, PCA was employed to reduce the number of items. Those variables which had a loading value of greater than 0.3 were retained(67).

Convergent and divergent validity was determined by employing Multi trait scaling analysis. Multi trait scaling analysis is a method used to examine convergent and divergent validity. It focuses on item to scale correlation(57). Scaling error was considered if items were consistently more strongly correlated with other scales which are not hypothetically assumed to correlate (15,34).

Clinical validity was checked using Mann-Whitney test to see whether the tools are able to detect differences between groups. For colorectal cancer patients, known groups that were used for comparison were treatment intent, physical function and stoma (34). Patients were classified as having better and worse physical function based on a median value of physical scale of the core questionnaire. Better physical function stands for ≥ 43.3 scores whereas worse physical function represents scores of < 43.3 (68). Body image, anxiety, sore skin and embarrassment scores were hypothesized to be higher in stoma patients. Similarly, curative and better physical function were expected to score lowers for the symptom items and scales. Comparison groups for

esophagogastric cancer patients were treatment intent and physical function (better and worse represent≥ 46.7 and < 46.7 scores respectively) (35). And curative and better physical functions were hypothesized to score lower for the symptom items and scales.

The correlations between scales and single items of CR-29 and OG-25 and C-30 were determined using spearman's correlation coefficient. A correlation coefficient between 0.40 and 0.6 was considered as moderate correlation. Similarly, if the correlation exceeded 0.6, it was considered as strong (34,35,59,69). In colorectal cancer patients, physical function was expected to show moderate correlations with pain (dysuria, abdominal pain, and buttock pain) and stoma care problems. Similarly, emotional scale was also hypothesized to show moderate correlations with body image, anxiety, and embarrassment scale and items. Likewise, social function was expected to show moderate correlations with flatulence, faecal incontinence, urinary incontinence, and sexual function(70).

A p- value less than 0.05 was adjusted as the level of statistical significance. The result of the reliability, validity and PCA results were presented using tables.

4.10.1 Scoring procedure

All scales and items were transformed in to a 0-100 score as per the manuals (71,72). According to the manuals, higher score for functional and global health status show high level of functioning and high quality of life respectively. However, high score for symptom or item indicate high level of problems.

For all scales, the Raw Score (RS) is the mean of the component items.

Range is calculated by subtracting the minimum possible value from the maximum possible value of raw score.

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

Then for Functional scales: Score = (1-(RS-1)/range) x 100

For Symptom scales / items and Global health status / QoL: Score = (RS-1)/range) x 100.

4.11 Ethical considerations

Ethical clearance was obtained from the ethical clearance committee of Addis Ababa University (AAU) College of health science, school of public health ethical review committee to conduct the research. Permission was secured from EORTC research group through online from https://qol.eortc.org/form to use the questionnaires. Informed written consent was taken from all participants after getting information about the purpose of the study, confidentiality, benefit, the risk and the right not to be participated and the right to withdraw at any time. The participant was told that they would not suffer any consequences if they chose not to participate in the study. Information was given that they would not get direct benefit. Confidentiality of the participants was kept by using codes and locking the data.

4.12 Dissemination of the result

Result of the study will be presented through AAU College of Health Science School of Public Health for the partial fulfillment of the degree of master of Public Health in Epidemiology and Biostatistics. The result will be submitted to a peer review journal for publication and copy of the result will be offered to Ministry of Health and Tikur anbessa hospital.

5. Result

5.1. Socio-demographic characteristics of respondents

A total of 316 participants were included in this study with median age of 48 (IQR =17.75). A round 108 (34%) participants had no formal education, while a quarter (25%) of respondents attended college. 166 (52.5%) of the respondents were males and 193 (61.1%) of them were married. Around 90 (28.5%) respondents were employed. More than half (59.5%) of respondents came from Addis Ababa followed by Oromia 65 (20.6%) and Amhara 35 (11%) regions.

Table 1, Socio-Demographic characteristics of respondents in Tikur Anbessa Hospital, Addis Ababa, 2020

Variable	Category	Frequency (n=316)	Per cent (%)
Sex	Male	166	52.53
	Female	150	47.47
Educational status	No formal education	108	34.18
	Primary education	78	24.68
	Secondary education	51	16.14
	College and above	79	25.00
Occupation	Farmer	34	10.76
	Employed	90	28.48
	House wives	104	32.91
	Retired	22	6.96
	Student	30	9.49
	Merchant	36	11.39
Region	Addis Ababa	188	59.49
	Oromia	65	20.57
	Amhara	35	11.08
	Other	28	8.86
Marital status	Married	193	61.07
	Single	56	17.72
	Divorced	33	10.44
	Widowed	34	10.76
Age	18-45	132	41.77
	46-65	170	53.80
	>65	14	4.43

5.2. Clinical characteristics of respondents

One hundred fifty-eight colorectal and 158 oesophagogastric patients were included. From colorectal cancer participants, rectal cancer accounted for 85 (53.8%) respondents. On the other

hand, esophageal cancer accounted for 112 (85%) oesophagogastric respondents. About 78 (49.40%) of colorectal respondents were on chemotherapy alone. Similarly, a quarter of oesophagogatric (24.70%) patients were on chemotherapy alone. Three-fourth of the respondents (75.95%) took treatments with palliative intent. The majority of (72.2%) colorectal respondents were stage four cancer patients. Similarly, three-fourth of (74.4%) esophagogastric patients were stage four cancer patients.

Table 2, Clinical characteristics of respondents in Tikur Anbessa Hospital, Addis Ababa, 2020

Variables	Category	Frequency	Per cent (%)
Colorectal cancer patients (N= 158)			
Cancer site	Colon	73	46.20
	Rectum	85	53.80
Type of treatment	Chemotherapy	78	49.40
	Surgery and Radiotherapy	16	10.10
	Chemotherapy and surgery	34	21.50
	Chemotherapy and Radiotherapy	17	10.80
	CSR	12	7.60
	Radiotherapy	1	0.60
Treatment intent	Curative	38	24.10
	Palliative	120	75.90
Cancer stage	Stage I	7	4.4
	StageII	24	15.2
	StageIII	13	8.2
	StageIV	114	72.2
Oesophagogastric cancer patients (N=158)			
Cancer site	Esophageal	112	70.90
	Gastric	46	29.10
Type of treatment	Chemotherapy	39	24.70
	Chemotherapy and surgery	36	22.80
	Surgery and Radiotherapy	19	12.00
	Chemotherapy and Radiotherapy	40	25.30
	Radiotherapy	14	8.90
	CSR	10	6.30
Treatment intent	Curative	38	24.10

	Palliative	120	75.90
Cancer stage	Stage I	12	7.6
	StageII	19	12.0
	StageIII	10	6.3
	Stage IV	117	74.1

CSR= Chemotherapy, Surgery and Radiotherapy

5.3. Acceptability of EORTC QLQ CR-29 and EORTC QLQ OG-25

The acceptability of the tools was assessed in term of response rate, missing data and time needed to complete the questionnaire**.** The EORTC-CR-29 along with EORTC-30 questionnaire took an average of 20 minutes. Similarly, EORTC-OG25 took an average of 15 minutes. There was no missing response to the questionnaires. In general, the tools were found to be acceptable

5.4. Principal Component Analysis result for EORTC QLQ CR-29 tool

A separate PCA was carried out for the functional and symptom scales. The functional scale contains five items. On the other hand, the symptom scale contains eighteen items. The Kaiser-Meyer-Olkin measure of sampling adequacy was above the recommended value of 0.5 and Bartlett's test of sphericity was significant ($p < 0.05$) for both scales. Given these overall indicators, Principal component analysis was conducted with all the items of functional and symptom scales.

The criteria to retain component were parallel analysis and scree plot. For the functional scale, the scree plot showed that the break point happened after the six component suggesting taking six components. On the other hand, parallel analysis indicated taking five components. Finally, six components were retained and they explained 71 per cent of the variance (see Annex 5). Similarly, the scree plot and the parallel analysis for the functional scale suggested taking two components. And the retained components explained 68 % of the variance (see Annex 5).

Since the un-rotated data had variables which loaded on more than one component, the data was subjected to varimax rotation to simplify and clarify the data structure. The criteria for deleting items within a component were items with factor loading lower than 0.3, a cross loading item that loaded at 0.3 or higher on two or more components, and items loaded in to components which they were not assumed to hang on. From the symptom scale, the original stool frequency

and urinary frequency sub-scales were reproduced. On the other hand, from the functional scale, body image was reproduced but had lower items. However, the blood and mucus scale was not reproduced.

PCA finding evidenced the unidimensionality of the tool. The un-rotated first component explained more than 20 % of the variance. It also suggested reducing the body image scale items in to smaller numbers. But based on different literature, it is recommended to have at least three items in the scale(73). Thus, we retained the item. And the remaining results use the original items and scales classification.

5.5. Principal Component Analysis result for EORTC QLQ OG-25 tool

The Kaiser-Meyer-Olkin measure of sampling adequacy was above the recommended value of 0.5 and Bartlett's test of sphericity ($p < 0.05$). A separate PCA was conducted for each scale. The criteria used to retain components were Eigen value greater than one and parallel analysis. For all scales, the criteria suggested retaining one component suggesting the unidimensionality of the scales. The items loading in the retained components was greater than 0.3(see Annex 5). This means all items in a scale highly correlate with the retained component. The retained components also explained more than 45 % of the variance which further confirmed the unidimensionality of the scales.

Table 3, Principal component analysis of EORTC QLQ OG 25 scales in Tikur Anbessa Hospital, Addis Ababa, 2020

	Initial Eigenvalues				Random Eigenvalues		
Scale	**Component**	**Total**	**% of variance**	**Cumulative %**	**Root**	**means**	**percentile**
Dysphagia	1	1.84	61.51	61.51	1	1.13	1.23
	2	0.79	26.44	87.95	2	0.99	1.03
	3	0.36	12.05	100	3	0.88	0.95
Eating	1	1.84	45.90	45.90	1	1.18	1.28
	2	0.89	22.24	68.14	2	1.05	1.11
	3	0.74	18.61	86.75	3	0.94	1
	4	0.53	13.24	100	4	0.83	0.90
Reflux	1	1.54	77.01	77.01	1	1.07	1.20
	2	0.46	22.99	100	2	0.93	0.99
Odynophagia	1	1.24	62.07	62.07	1	1.07	1.20

	2	0.76	37.93	100	2	0.93	0.99
Pain and discomfort	1	1.50	75.10	75.10	1	1.07	1.20
	2	0.50	24.90	100	2	0.93	0.99
Anxiety	1	1.48	74.13	74.12	1	1.07	1.20
	2	0.52	25.9	100	2	0.93	0.99

5.6. Reliability of EORTC QLQ CR-29

The reliability of the tool was examined based on Cronbach's alpha coefficients value (alpha≥0.70). Alpha value was calculated for the whole tool and each scale. For the whole tool, it was 0.56. As presented in table 4, all of the scales had alpha value greater than or equal to 0.7 except for mucus and blood in stool scale (0.47). On the other hand, the urinary frequency had the highest alpha value (0.91) which was followed by stool frequency (0.85).

Table 4, Cronbach's Alpha value for four multi item scales of EORTC QLQ CR-29 tool in Tikur Anbessa Hospital, Addis Ababa, 2020.

Scale name	Number of items	Cronbach's alpha coefficients
Urinary frequency	2	0.91
Mucus and blood in stool	2	0.47
Body image	3	0.70
Stool frequency	2	0.85

5.7. Reliability of EORTC QLQ OG-25

The total Cronbach's α coefficient was 0.88 ranging from 0.39-0.71 in the scales. Internal consistency reliability for Reflux reached the 0.7 criterion. And the internal consistency alpha value for Dysphagia, Eating, Pain and Discomfort and Anxiety was above 0.6. However, the Cronbach's alpha coefficient for Odynophagia was low.

Table 5, Cronbach's Alpha value for six multi item scales of EORTC QLQ CR-OG tool in Tikur Anbessa Hospital, Addis Ababa, 2020.

Scale name	Number of items	Cronbach's alpha coefficients
Dysphagia	3	0.67
Eating	4	0.60
Reflux	2	0.70
Odynophagia	2	0.39
Pain and discomfort	2	0.67
Anxiety	2	0.65

5.8. Construct Validity

5.8.1. Convergent and divergent validity result of multi-trait scale analysis for EORTC QLQ CR-29

Before running multi- trait scale analysis, the data was checked for normality using box-plot. It was found to violate the assumption. Therefore, Spearman's rho correlation was used to determine the correlation. A p- value less than 0.05 was set as the level of statistical significance. Convergent and divergent validity was indicated by item-own scale and item-other scale correlation. The item- own scale correlation was over 0.4 for all scales. Similarly, item-own correlation for all scales was higher than item-other scale correlation. As seen in table 6, the Urinary frequency item-own correlation is near to one. On the other hand, its item-other scale correlation was around 0.3. Furthermore, the remaining all scales have item-own correlation above 0.4 and item other scale correlation below 0.4. By looking at item-own scale correlation, one might conclude that the tool scales met convergent validity assumption. However, when a correction for overlap was made, item- own correlation for the blood and stool mucus scale dropped to 0.22. This suggested that Blood and Mucus in stool scale didn't fulfill the criteria for divergent and convergent validity. All in all, Urinary frequency, Body image and Stool frequency scales met the criteria for convergent and divergent validity.

Table 6, Convergent and Divergent validity for EORTC QLQ CR-29 scales in Tikur Anbessa Hospital, Addis Ababa, 2020.

Scale	Items number	Item- own scale correlation	Item- own scale correlation after correction overlap	Item-other scale correlation	P-value
Urinary frequency	31,32	0.942-0.955	0.811	-0.328-0.339	0.001
Blood and Mucus in stool	38,39	0.741-0.792	0.244	-0.308-0.350	0.001
Stool frequency	52,53	0.924-0.930	0.732	-0.326-0.346	0.001
Body image	45-47	0.749-0.813	0.509- -0.553	-0.395- -0.186	0.001

5.8.2. Convergent and divergent validity result of multi-trait scale analysis for EORTC QLQ OG-25

Since the data violated normality assumption, Spearman's rho was used to determine the correlation between item-own scale correlation and item-other scale correlation. A p- value less than 0.05 was set as level of significant. The item- own scale correlations were over 0.4 for all scales. But when correction for overlap considered, Dysphagia, Eating and Odynophagia scales had correlations less than 0.4. Four scales' item-own scale correlations were lower than item-other scale correlations. This suggested that the divergent validity was not fulfilled for all scales. Item 31, for instance, had item-own correlation of 0.36. But its item-other scale correlations ranged from 0.19-0.52.

Similarly, item 36 had item-own scale correlation of 0.35 and item-other scale correlations between 0.29-0.53. Furthermore, item 40 and 41 item-other scale correlations' ranged from 0.18-0.51. But their item-own scale correlation was 0.25. Moreover, item 44 and 45 had item-own scale correlation of 0.48. And their item-other scale correlations lay between 0.180 - 0.525. Three scales in the tool had item-own correlations above 0.4. On the other hand, the divergent validity result revealed that four scales' item-other scale correlations were greater than item-own scale correlation.

Table 7, Convergent and Divergent validity for EORTC QLQ OG 25 scales in Tikur Anbessa Hospital, Addis Ababa, 2020.

Scale	Items number	Item- own scale correlation	Item- own scale correlation after correction overlap	Item-other scale correlation	P-value
Dysphagia	31,32,33,	0.69-0.84	0.36-0.65	0.16-0.52	<0.05
Eating	34,35,36,37	0.64-0.69	0.33-0.40	0.19-0.53	<0.05
reflux	38,39	0.87-0.88	0.54	0.18-0.41	<0.05
odynopagia	40,41	0.77-0.80	0.24	0.16 -0.51	<0.05
Pain and discomfort	42,43	0.85-0.88	0.51	0.16 -0.39	<0.05
anxiety	44,45	0.85-0.87	0.49	0.16 -0.52	<0.05

5.9. The correlation between the core EORTC QLQ C-30 and the tools

5.9.1. The correlation between EORTC QLQ C-30 and CR-29

The correlation between CR-29 and C-30 was examined. And the correlation between CR-29 and the functional scales ranged from -0.46-0.57. The highest correlation(r=0.57) was seen between Body image scale of CR-29 and Emotional scale of the core questionnaire. The correlation between Physical function of the core questionnaire and CR-29 lay between -0.42-0.43. This scale had highest positive correlation with Body image whilst its highest negative correlation was seen with Flatulence. The correlation between Emotional domain and CR-29 ranged from -0.40-0.57. As mentioned earlier, its highest correlation was noted with Body image. Furthermore, its highest negative correlation was observed with Stool frequency(r=-0.40) and Dysuria(r=-0.40). Likewise, Social functioning domain correlation' with CR-29 ranged from -0.42-0.32. Its highest correlation was seen with Urinary incontinency. On the other hand, the correlation between Global quality of life scale in the C-30 and CR-29 lay between -0.19-0.24.

The correlation between CR-29 and symptom scales and items of C-30 ranged from -0.41-0.45. Its highest positive correlation was seen between Dysuria and Appetite loss. Pain scale had a moderate correlation with only C-29 Taste item(r=0.44). Dyspnea scale's correlation ranged from-0.41-0.44. Its highest correlation was observed with Dysuria and its highest negative

correlation was seen with Body image. Insomnia and Appetite loss had correlations over 0.4 with Abdominal pain(r=0.43) and Dysuria(r=0.45). Otherwise, Constipation, Diarrhea, Nausea and Vomiting, and Financial problem correlations with CR-29 were below 0.4(see Annex 6).

In general most of correlations between EORTC QLQ C30 and CR29 were below 0.4. Body image, Flatulence, Faecal incontinence, Dysuria, Stool frequency, Urinary incontinency, Taste and Abdominal pain showed correlations above 0.4. The finding of this correlation test suggests that the tools are meant to cover different dimensions of quality of life. Therefore, the core questionnaire should be used along the specific modules.

5.9.2. Correlation between EORTC QLQ C-30 and OG-25

The highest correlation between OG-25 and C-30 was observed between Fatigue and Trouble with talking item(r=0.62). The correlations between Fatigue and OG-25 ranged from -0.11-0.62. It had correlations above 0.4 with Eating, Reflux and Body image. The correlations between Nausea and Vomiting and OG-25 extended from 0.18-0.48. Its highest correlation was seen with Reflux. It also had a correlation above 0.4 with Body image. Likewise, the correlation between Pain and OG-25 lay between -0.04-0.55. Its highest correlation was observed with Eating scale. Furthermore, it had moderate correlations with Reflux, Body image, Trouble with coughing, and talking scales and items. Similarly, Dyspnea had a moderate correlation (r=0.47) with only OG 25 Trouble with coughing item. Insomnia's correlations with OG 25 ranged from 0.04-0.48. The highest correlation was seen with Reflux, Body image and Trouble with coughing. It had also moderate correlations with Trouble with talking (r=0.47) and Eating (r=0.45). Appetite loss had moderate correlations with Eating(r=0.49) and Reflux(r=0.46) scales. Constipation had a moderate correlation with only OG-25 Reflux scale (r=0.47). In addition, Financial problem had moderate correlations with trouble with coughing (r=0.44) and choked when swallowing(r=0.42) items (see Annex 6).

As it can be seen in table 8, almost all correlations between OG-25 items and scales and C-30 functional scales were negative. The highest correlation was noted between Trouble with coughing and Emotional scale. In addition, Physical, role, emotional, cognitive and social functions had correlations above 0.4 with Eating, Reflux, Anxiety, Dry mouth, Body image, Choked when coughing, Trouble with coughing and talking, and Eating with others scales and

items. Conversely, none of OG 25 items and scales had moderate correlation with global quality of life scale. This finding indicates that the core questionnaire should be used together with the specific module as there are some moderate correlations and weak correlations.

Table 8, Correlation between the EORTC QLQ-OG 25 and functional subscales of the EORTC QLQ-C30, in Tikur Anbessa Hospital, Addis Ababa, 2020.

EORTC-OG 25 scales and items	PF	RF	EF	CF	SF	QOL
Dysphagia	-0.3**	-0.26**	-0.30**	-0.34**	-0.40**	-0.01
Eating	-0.57**	-0.49**	-0.52**	-0.40**	-0.25**	0.03
Reflux	-0.44**	-0.34**	-0.44**	-0.31**	-0.30**	-0.07
Odynophagia	-0.29**	-0.17*	-0.24**	-0.26**	-.36**	0.01
Pain and discomfort	-0.27**	-0.15	-0.33**	-0.29**	-0.22**	-0.03
Anxiety	-0.59**	-0.25**	-0.38**	-0.20*	-0.17*	0.01
Eating with others	-0.35**	-0.47**	-0.45**	-0.33**	-0.24**	0.06
Dry mouth	-0.49**	-0.39**	-0.56**	-0.28**	-0.43**	0.00
Trouble with taste	-0.12	-0.01	-0.05	-0.29**	-0.22**	-0.02
Body image	-0.42**	-0.41**	-0.55**	-0.36**	-0.38**	-0.02
Trouble swallowing saliva	-0.31**	-0.22**	-0.19*	-0.27**	-0.40**	0.04
Choked when swallowing	-0.43**	-0.41**	-0.40**	-0.43**	-0.42**	0.02
Trouble with coughing	-0.48**	-0.41**	-0.65**	-0.41**	-0.52**	0.17*
Trouble talking	-0.54**	-0.62**	-0.53**	-0.31**	-0.21**	0.06
Weight loss	-0.26**	-0.20*	-0.39**	-0.52**	-0.39**	-0.08
Hair loss	-0.12	-0.19*	-0.02	-0.19*	0.06	-0.00

Physical function=PF, Role function=RF, Emotional function= EF, Cognitive function= CF, Social function= SF, Quality of life =QOL* Correlation is significant at the 0.05 level , **. Correlation is significant at the 0.01 level

5.10. The clinical validity of the tools

5.10.1. The clinical validity of EORTC QLQ CR-29 tool

To assess the clinical validity of the tool, comparison of scores of multi-item scales and single items of EORTC 29 among three clinically distinct groups were done. Since the data violated the normality assumption, Mann-Whitney test was employed. These three groups were treatment intent, presence of stoma and physical function. This study hypothesized that patients with stoma had higher symptom score for embarrassment and sore skin, and lower functional score for anxiety and body image items and scale. Similarly, patients with worse physical health and palliative patients were expected to have higher scores for the symptom items and scales and lower score for functional scales and items

The Mann-Whitney test revealed that there were no significant differences between the curative and the palliative treatment groups in any of the scores of the CR-29 scales or items. In patients with and without a stoma, the differences were noted in the Anxiety, Embarrassment, Urinary frequency, Blood and Mucus in stool, Abdominal pain, Dry mouth, Taste and Flatulence. And the presence of stoma deteriorated quality of life with Urinary frequency, Flatulence, Embarrassment and Anxiety. On the other hand, patients who didn't have stoma scored higher symptom for Blood and Mucus in the stool, Hair loss, Abdominal pain and Tastes. As for patients with better physical function and worse physical function, the differences were observed in the Body image, Anxiety, Dysuria, Bloating, Dry mouth, Hair loss, Taste, Flatulence, Faecal incontinence, Urinary incontinence, and Abdominal pain. As hypothesized, people with better physical function had higher score for functional items and scale and lower score for symptom items and scales (See Annex 7). This suggested the clinical validity of the tool.

5.10.2. The clinical validity of EORTC QLQ OG-25 tool

Clinical validity was checked by comparing the scores of multi-item scales and single items of EORTC OG-25 among two distinct groups. As non-normality was seen in the data, Mann-Whitney test was carried out. The groups were formed based on treatment intent and physical function. Patients on curative intent and with better physical function were hypothesized to score lower for the scores. Dysphagia, Eating, Anxiety, Dry mouth and Trouble with coughing items and scales were able to distinguish patients on palliative and curative treatment. In contrast to

what was hypothesized, patients on curative care had significantly lower scores for the mentioned items and scales. As for the physical function, except Pain and Discomfort and Trouble with taste items, all other scales and items discriminated patients who had better physical function and worse physical function. Patients with better physical function had lower score for the items. This revealed the clinical validity of the tool.

Table 9, Known group comparisons: scales and items in the EORTC QLQ OG-25 for clinically distinct groups, tool in Tikur Anbessa Hospital, Addis Ababa, 2020.

	Treatment intent			Physical function		
EORTC OG 25	**Curative n=38**	**Palliative n=120**	**P-value**	**Lower n=81**	**Better n=77**	**p-value**
Dysphagia	93.68	75.01	0.03	90.23	68.21	0.00
Eating	96.59	74.09	0.01	102.52	55.29	0.00
Reflux	91.72	75.63	0.06	93.17	65.12	0.00
Odynophagia	88.66	76.60	0.15	88.57	69.96	0.01
Pain and discomfort	82.80	78.45	0.60	84.57	74.16	0.14
Anxiety	96.54	74.10	0.01	101.09	56.79	0.00
Eating with others	87.13	77.08	0.16	91.48	66.90	0.00
Dry mouth	92.82	75.28	0.03	93.28	65.01	0.00
Trouble with taste	91.32	75.76	0.06	84.93	73.79	0.11
Body image	91.53	75.69	0.05	94.10	64.14	0.00
Trouble swallowing saliva	85.82	77.50	0.31	88.84	69.68	0.01
Choked when swallowing	93.95	74.93	0.02	90.83	67.58	0.00
Trouble with coughing	90.76	75.93	0.01	93.18	65.11	0.00
Trouble talking	88.07	76.79	0.17	99.41	58.56	0.00
Weight loss	85.43	77.62	0.33	88.17	70.38	0.01
Hair loss	29.83	35.82	0.28	38.36	29.31	0.05

6. Discussion

The purpose of this study was to check the validity of EORTC QLQ CR-25 and OG-25 tools in Ethiopian context. The reliability, unidimesionality, convergent, divergent and clinical validity of the tools were checked. The first component in the tools explained greater than 20 % of the variance in the data. The scales in the tool had alpha values greater than or equal to 0.7 except for Blood and Mucus in stool, Dysphagia, Eating, Odynophagea, Pain and Discomfort, and Anxiety scales. The item-own scale correlations were greater than 0.4 and the item-other scale correlations were below the item-own scale correlations except for Blood and Mucus in stool, Dysphagia, Eating, Odynophagea and Anxiety scales. Further, the tools discriminated people in different known groups. The correlations between the core questionnaire and the tools ranged from weak to strong.

The Principal component analysis finding of CR-29 found similar item and scale classification like the original study(34) except for the Blood and Mucus in stool scale. In contrast to our finding, the Dutch study supported the Blood and Mucus in stool scale formation. This difference might be explained by the fact that the current study used stringent component retention criteria (74) whereas they used Eigen value criteria. They didn't also mention about the variance explained by the first component. This might contribute for the disparity observed in our study and their study.

Likewise, PCA was also employed in EORTC QLQ OG-25 tool. And the scales in the tool were found to be unidimensional. However, none of the previous studies(12,16) tried to assess the unidmensionality of the scales. Assessing the unidmensionality of a tool with internal consistency is not enough because Cronbach-alpha values are affected by the number of questions in a scale(57); therefore, unidmensionality assessment with a strong method is very crucial.

In our study, the internal consistency for the colorectal ranged from 0.4-0.91. All scales had alpha values above 0.7 except for Blood and Mucus in stool scale. This finding concurs with the Dutch and the original studies(34,59). In contrast, the Korean and Taiwan studies (15,58) had Cronbach-alpha values greater than 0.7 for all scales. On the other hand, the Spanish and Chinese

(13,14) studies had alpha values greater than 0.7 only for one scale. Ceiling and flooring have effect on alpha values estimation (75). This means if most of the respondents achieve the lower or higher scores for the items, this may reduce variability in the data which, in turn, lowers alpha value. Thus, the difference might be explained by a low variability in Blood and Mucus in stool scale in the studies, which might lower the correlations and the value of alpha.

In EORTC QLQ OG-25 module, the internal consistency values ranged from 0.39-0.7. Except the Reflux scale, alpha values for all scales lay below 0.7. This is inconsistent with the findings of Polish (0.79-0.91), Mexican(0.7–0.83) and the original studies (0.67–0.87) (12,16,35). Though alpha values for these studies were above 0.7, the original study had alpha value less than 0.7 for Reflux scale. As mentioned earlier, the lower variability in items score of our data might contribute to the difference.

For EORTC QLQ CR-29, all items correlations within their scales were greater than 0.4 except for Blood and Mucus in stool. This goes in line with the Spanish study (14). However, this is inconsistent with the previous findings (13,15,34,58,59). Different findings reveal that limited variability in item score has effect on a correlation (75). Besides, this result is supported by the PCA finding which didn't support the scale formation of item39 and 38. Furthermore, the item-other scale correlation for this scale result didn't support the divergent validity.

The correlation between item-own scale and item-other scale correlations for OG-25 items supported the convergent and divergent validity for all scales. This finding concurs with the previous findings(12,16,35). However, when correction for overlap was made, only two of the scales fulfilled the divergent and convergent validity. The possible explanation for this disparity is that if correction for overlap is not done, the correlation may tend to be misleadingly high (57). Therefore, this finding suggests doing correction for overlap while calculating items-own correlation.

For EORTC QLQ CR-29, the clinical validity was assessed by comparing known groups. Our finding is consistent with previous studies (13,14,34,59), the tool was found to differentiate the groups. However, Body image and Sore skin items did not discriminate patients with stoma and without stoma. This is inconsistent to the previous findings(13,14,34,59). The difference might be due to age difference. Based on a study, older patients were found to give less value for body

image(76). In the current study, patients in stoma groups were older in age than the non-stoma groups. Even in other Ethiopian study (37) Body image didn't differentiate known groups in cancer patients.

In addition, Sore skin didn't differentiate patients with stoma and non-stoma patients. This might be explained by the educational level because most of the stoma patients had secondary and above education. And education was identified to have correlation with skin related complication(77).

On the other hand, contrary to the previous findings(13,14,34,59), Hair loss, Blood and Mucus in tool, Taste, Flatulence and Urinary frequency discriminated the groups. From them, Flatulence and Urinary frequency have higher scores in stoma patients. This might be explained by the fact that most of the patients with stoma were on radiotherapy. Genito-urinary dysfunction is from the known side effects of radiotherapy(78). Whereas, Hair loss, Blood and Mucus in stool, and Taste items were higher in non- stoma patients. This might be explained by the fact that most of non-stoma patients were on chemotherapy, and these symptoms are related to chemotherapy associated side effect (79,80).

Conversely, treatment intent didn't differentiate the groups. This is inconsistent with the original and Dutch studies (34,59). In these studies, Blood and Mucus in stool, Buttock pain, Dry mouth, Dyspareunia and Hair loss differentiated the groups.

Similarly, the clinical validity of EORTC QLQ OG-25 was evaluated. The groups were partitioned based on treatment intent and physical function. Dysphaga, Eating, Anxiety, Dry mouth, Body image, Choked when swallowing and Trouble with coughing items and scales differentiated the groups. In contrast to the previous study(12), these items and scales in curative patients showed higher symptoms. The reason for this might be explained by the fact that most of the curative patients in this study took surgery. The mentioned symptoms are the common post-operative complications(81).

On the other hand, physical function differentiated the group for all scales and items except for Pain and Discomfort and Trouble with taste items. This might be explained by the lower sample size of gastric patients because these items are more common in gastric cancer patients(82).

Unlike the current study, the Polish study (16) showed that Anxiety, Body image, Hair loss, Weight loss and Trouble with talking didn't differentiate the groups. The disparity with our data might be explained by the fact that they included small sample size (N=98). In contrast to the current study, the Mexican study (12) also revealed that Reflux, Anxiety, Trouble with coughing, and Body image didn't discriminate the groups. The possible explanation for the variation might be that they used different tool to assess physical function. To our knowledge, the comparability of the tools is not known.

The correlation between EORTC QLQ C-30 and CR-29 ranged from weak to moderate. The highest correlation was observed between Emotional scale and Body image. This concurs to studies conducted in Korean and Spanish (14,15), where they showed moderate correlation for the domains. But this is inconsistent with the original and Dutch studies(34,59) where they didn't find moderate correlation. Based on a study, Emotional scales and Body image have correlations in colorectal cancer patients(70). Thus, it is expected to show correlation. And the variation between our study and their studies might be explained by variability in the items, and this might affect the magnitude of the true correlation.

Even though Sexual function, Stool incontinence and Flatulence domain were hypothesized to show moderate correlations with Social function, this study didn't find moderate correlations between them. This is in line with the previous findings(13,34). Likewise, Physical function was expected to show moderate correlations with Pain and Stoma care problem. However, in line with the original, Dutch, and Chinese studies(13,34,59), the current study didn't find moderate correlations between Physical function and Pain and Stoma care items.

Contrary to the original study (34), our finding had also moderate correlations for some items. Surprisingly, in this study, Taste and Pain items showed moderate correlations. This can be explained by the fact that pain and taste use the same circuit while transmitting signal to our brain(83,84). Furthermore, unlike the other studies, Dysuria and Dyspena showed correlations. Based on literature, Emotional function has correlation with Dysuria and Dyspena(85,86). This third variable might hide the true correlation between the two items. Otherwise the other correlation findings were seen in other studies. In general, this correlation finding suggested that the two tools should be used together. One tool cannot be used replacing the other.

The correlation between EORTC QLQ C-30 and OG-25 showed correlation above 0.4 for some items and scales and below 0.4 for the others. The strong correlation was observed between Fatigue and Trouble with talking. This is inconsistent to study conducted in Polish(16), where the highest correlation was seen between Anxiety and Emotional scales. The Mexican and original studies (12,35) didn't show the magnitude of correlations between the tools. Contrary to the previous studies(12,16,35), our finding didn't find moderate correlations between global health scale with OG-25 scales and items. The possible explanation could be that the global health question is a more general one and patients might give homogeneous answer, and this might reduce the magnitude of correlation. All in all, the correlation finding goes in line with other studies and suggests that the core questionnaires and the tools assess different dimensions of quality of life. Therefore, one tool should not be used replacing the other.

6.1. Limitation of the study

To increase the representativeness of this study, patients irrespective of their place of residence, treatment and disease stage were included. However, most of the patients were in end stage cancer, so the generalizablity of the finding for early stage patients cannot be ascertained. Secondly, most of the patients in the esophagogastric tool were esophageal and gastric cancer patients; therefore, to evidence the validity of the tool in gastro-esophageal junction cancer patients, it needs to be tested in larger population.

6.2. Strength of the study

During translation of the tools, every steps of EORTC translation procedure were followed and the whole processes were carried out under the supervision of the EORTC translation group. While assessing convergent and divergent validity, a correction for overlap was applied. Unidmensionality of the tools was also checked.

7. Conclusion and recommendation

7.1. Conclusion

The current study checked the validity and reliability of colorectal and oesophagogastric cancer tools in Ethiopian context. This study supported the clinical validity of the tools. It also found that these tools are meant to measure different dimensions of quality of life from the core questionnaire. Almost all scales in colorectal tool were reliable. Except the blood and mucus in stool scale, the divergent and convergent validity of all colorectal scales were supported. It was also found that that majority of oesophagogastric scales didn't have reliability above the recommendation except for reflux. From the esophagogastric tool, only reflux and pain and discomfort scales fulfilled the criteria for convergent and divergent validity.

7.2. Recommendation

Though EORTC QLQ CR-29 and OG-25 tools were supported for their clinical validity, the construct validity and the reliability are below the recommendation for some scales. Therefore, we recommend other researchers to do confirmatory test to evidence the scale and item classification of the tools. We also recommend other researchers to do test-retest while assessing reliability of the tools. Adapted and validated tool will help physician during decision making in treatment choice. Hence, we recommend the Ministry of Health to support a validation study to be conducted throughout the country to insure representativeness of the findings. It would also be good if researchers and clinicians use the core questionnaire along with the disease specific modules while assessing health related quality of life in colorectal and esophagogastric cancer patients.

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Annexes

Annex 1

1.1 Participant Information Sheet (English version)

Introduction

My name is …… I am working as data collector for master of public health student project in Addis Ababa University. We are conducting a research entitled "validating of European organization for research and treatment of cancer quality of life Questionnaire in Ethiopian colorectal and esophagogastric cancer patients".

Purpose of the study: - This study will examine the validity of the colorectal, esophagogastric and prostate cancer specific quality of life module of the European Organization for Research and Treatment of Cancer (EORTCQLQ-C29 and QLQ-OG 25) in Ethiopian colorectal and esophagogastric cancer patients.

Benefit: - There will have no direct benefit to you but based on the information you provide us, we will get a validated tool to assess health related quality of life among colorectal and esophagogastric cancer patients.

Risk: - I may ask you about your disease which may be personal information and may not be comfortable. However, the information you provide will have paramount importance to conduct this research.

Procedures: - If you agree to participate in the study, you will be asked to answer some questions about research related questions and yourself. The interview will take 25 minutes.

Your participation will be voluntary: - Your participation is purely based on your willingness and you have the right to choose not to take part in this study. If you choose to take part, you have the right to stop the interview at any time. If you are willing to participate or refuse or decide to withdraw later, you will not be subjected to any problems.

Confidentiality: - The information that you provide will be kept confidential by using codes and locking the data. No one will have access to the non-coded data except the investigators. The data will not be used for purposes other than the study.

Whom to Contact- If you have any questions, you may contact to the person stated below.

Lidya Genene - Tele: +25191266594

1.2 Consent form

I understand the purpose of the study. The study has been explained to me in the language that I understand. I have had the opportunity to ask questions and the questions I asked have been answered to my satisfaction. I consent voluntarily to be part of the study and understand that I have the right to withdraw from the study at any time.

Participant

Signature_____ Date_____

Interviewer

Name_____ Signature_____

Questionnaires number_____

Date of interview_____ Starting time_____ Completed_____

Annex 2

2.1 Questionnaire in English for colorectal cancer patients

Inclusion criteria

Pathologically confirmed colorectal patients who are ≥ 18 years and who can speak Amharic language

Exclusion criteria

Patients who have known psychiatric disorders

Hospital name----------

Hospital card no ----------

Part one

1. Socio-Demographic data

No	Variable	Response
1.1	Age	----------year
1.2	Sex	A, male B female
1.3	Educational status	A. Illiterate B. Read and write C. Primary education D. Secondary education E. College and above
1.4	Occupation	A, Farmer

		B, Housewife C, Employed D, Unemployed E, Retired F, Student G, Merchant G, Other(specify)----------
1.5	Residence	A. Addis Ababa B. Out of Addis Ababa(Specify the region) ---------
1.6	Marital status	A, Married B, Single C, Divorced D, widowed E, Other(specify)----------

Part two

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.

		Not at all	alittle	Quit a bit	Very much

1	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2	Do you have any trouble taking a long walk?	1	2	3	4
3	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4	Do you need to stay in bed or a chair during the day?	1	2	3	4
5	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
	During the past week:	Not at all	alittle	Quit a bit	Very much
6	Were you limited in doing either your work or other daily activities?	1	2	3	4
7	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8	Were you short of breath?	1	2	3	4
9	Have you had pain?	1	2	3	4
10	Did you need to rest?	1	2	3	4
11	Have you had trouble sleeping?	1	2	3	4
12	Have you felt weak?	1	2	3	4
13	Have you lacked appetite?	1	2	3	4
14	Have you felt nauseated?	1	2	3	4
15	Have you vomited?	1	2	3	4
16	Have you been constipated?	1	2	3	4

	During the past week:	Not at all		alittle		Quit a bit		Very much
17	Have you had diarrhea?	1		2		3		4
18	Were you tired?	1		2		3		4
19	Did pain interfere with your daily activities?	1		2		3		4
20	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1		2		3		4
21	Did you feel tense?	1		2		3		4
22	Did you worry?	1		2		3		4
23	Did you feel irritable?	1		2		3		4
24	Did you feel depressed?	1		2		3		4
25	Have you had difficulty remembering things?	Not at all		alittle		Quite a bit		Very much
26	Has your physical condition or medical treatment interfered with your family life?	1		2		3		4
27	Has your physical condition or medical treatment interfered with your social activities?	1		2		3		4
28	Has your physical condition or medical treatment caused you financial difficulties?	1		2		3		4
	For the following questions please circle the number between 1 and 7 that best applies to you							
29	How would you rate your overall	1 Very	2	3	4	5	6	7 Excellent

	health during the past week?	poor						
30	How would you rate your overall quality of life during the past week?	1 Very poor	2	3	4	5	6	7 Excellent

EORTC QLQ – CR29 ENGLISH

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

	During the past week:	Not at all	a little	Quite a bit	Very much
31	Did you urinate frequently during the day?	1	2	3	4
32	Did you urinate frequently during the night?	1	2	3	4
33	Have you had any unintentional release (leakage) of urine?	1	2	3	4
34	Did you have pain when you urinated?	1	2	3	4
35	Did you have abdominal pain?	1	2	3	4
36	Did you have pain in your buttocks/anal area/rectum?	1	2	3	4
37	Did you have a bloated feeling in your abdomen?	1	2	3	4
38	Have you had blood in your stools?	1	2	3	4

39	Have you had mucus in your stools?	1	2	3	4
40	Did you have a dry mouth?	1	2	3	4
41	Have you lost hair as a result of your treatment?	1	2	3	4
42	Have you had problems with your sense of taste?	1	2	3	4
	During the past week:	Not at all	alittle	Quit a bit	Very much
43	Were you worried about your health in the future?	1	2	3	4
44	Have you worried about your weight?	1	2	3	4
45	Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
46	Have you been feeling less feminine/masculine as a result of your disease or treatment?	1	2	3	4
47	Have you been dissatisfied with your body?	1	2	3	4
48	Do you have a stoma bag (colostomy/ileostomy)? please circle the correct answer)	Yes		No	
	During the past week:answer these questions ONLY IF YOU HAVE A STOMA BAG, if not please continue below:	Not at all	alittle	Quit a bit	Very much
49	Have you had unintentional release of gas/flatulence from your stoma bag?	1	2	3	4
50	Have you had leakage of stools from your stoma bag?	1	2	3	4
51	Have you had sore skin around your stoma?	1	2	3	4

52	. Did frequent bag changes occur during the day?	1	2	3	4
53	Did frequent bag changes occur during the night?	1	2	3	4
54	Did you feel embarrassed because of your stoma?	1	2	3	4
55	Did you have problems caring for your stoma?	1	2	3	4
Answer these questions ONLY IF YOU DO NOT HAVE A STOMA BAG:					
49	Have you had unintentional release of gas/flatulence from your back passage?	1	2	3	4
50	Have you had leakage of stools from your back passage?	1	2	3	4
51	Have you had sore skin around your anal area?	1	2	3	4
52	Did frequent bowel movements occur during the day?	1	2	3	4
53	Did frequent bowel movements occur during the night?	1	2	3	4
54	Did you feel embarrassed because of your bowel movement?	1	2	3	4
For men only:					
56	To what extent were you interested in sex?	1	2	3	4
57	Did you have difficulty getting or maintaining an erection?	1	2	3	4
For women only:					

59	To what extent were you interested in sex?	1	2	3	4
59	Did you have pain or discomfort during intercourse	1	2	3	4

Part three

Clinical data extracted from colorectal cancer patients' medical chart

1	Cancer site	1. Colon 2. Rectal
2	Started treatment	A. Yes B. No
3	If yes, for question number above what type of treatment?	A. Surgery B. Radiotherapy C. Chemotherapy
4	Treatment outcome	A, Curative B, Palliative
5	Stage	A. Stage 0 B. Stage I C. Stage II D. Stage III E. Stage IV F. Unknown
6	Primary Tumor size	A. Tx B. T0 C. T1 D. T2

		E. T3 F. T4 G. Unknown
7	Regional lymph node	A. Nx B. N0 C. N1 D. N2 E. N3 F. N4 G. Unknown
8	Distant metastasis	A. Mx B. M0 C. M1 D. Unknown

2.2 Questionnaire in English for esophagogastric cancer patients

Inclusion criteria

Pathologically confirmed esophagogastric cancer patients who are ≥ 18 years and who can speak Amharic language.

Exclusion criteria

Patients who have known psychiatric disorders

Hospital name----------

Hospital card no ----------

Part one

1. Socio-Demographic data

No	Variable	Response
1.1	Age	----------year
1.2	Sex	A, male B female
1.3	Educational status	A. Illiterate B. Read and write C. Primary education D. Secondary education E. College and above
1.4	Occupation	A, Farmer B, Housewife C, Employed D, Unemployed E, Retired F, Student G, Merchant G, Other(specify)----------
1.5	Residence	A. Addis Ababa B. Out of Addis Ababa(Specify the

		region) ---------
1.6	Marital status	A, Married B, Single C, Divorced D, widowed E, Other(specify)----------

Part two

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.

		Not at all	alittle	Quit a bit	Very much
1	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2	Do you have any trouble taking a long walk?	1	2	3	4
3	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4	Do you need to stay in bed or a chair during the day?	1	2	3	4
5	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
	During the past week:	Not at all	alittle	Quit a bit	Very much

6	Were you limited in doing either your work or other daily activities?	1	2	3	4
7	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8	Were you short of breath?	1	2	3	4
9	Have you had pain?	1	2	3	4
10	Did you need to rest?	1	2	3	4
11	Have you had trouble sleeping?	1	2	3	4
12	Have you felt weak?	1	2	3	4
13	Have you lacked appetite?	1	2	3	4
14	Have you felt nauseated?	1	2	3	4
15	Have you vomited?	1	2	3	4
16	Have you been constipated?	1	2	3	4
	During the past week:	Not at all	alittle	Quit a bit	Very much
17	Have you had diarrhea?	1	2	3	4
18	Were you tired?	1	2	3	4
19	Did pain interfere with your daily activities?	1	2	3	4
20	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21	Did you feel tense?	1	2	3	4
22	Did you worry?	1	2	3	4
23	Did you feel irritable?	1	2	3	4
24	Did you feel depressed?	1	2	3	4
25	Have you had difficulty remembering things?	Not at all	alittle	Quite a bit	Very much

26	Has your physical condition or medical treatment interfered with your family life?	1		2		3		4
27	Has your physical condition or medical treatment interfered with your social activities?	1		2		3		4
28	Has your physical condition or medical treatment caused you financial difficulties?	1		2		3		4
	For the following questions please 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 Very poor	2	3	4	5	6	7 Excellent
30	How would you rate your overall quality of life during the past week?	1 Very poor	2	3	4	5	6	7 Excellent

EORTC QLQ – OG25 ENGLISH

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

		Not at all	alittle	Quit a bit	Very much
1	Have you had problems eating solid foods?	1	2	3	4
2	Have you had problems eating liquidized or soft foods?	1	2	3	4

3	Have you had problems drinking liquids?	1	2	3	4
4	Have you had trouble enjoying your meals?	1	2	3	4
5	Have you felt full up too quickly after beginning to eat?	1	2	3	4
6	Has it taken you a long time to complete your meals?	1	2	3	4
7	Have you had difficulty eating?	1	2	3	4
8	Have you had acid indigestion or heartburn?	1	2	3	4
9	Has acid or bile coming into your mouth been a problem	1	2	3	4
10	Have you had discomfort when eating?	1	2	3	4
11	Have you had pain when you eat?	1	2	3	4
12	Have you had pain in your stomach area?	1	2	3	4
13	Have you had discomfort in your stomach area?	1	2	3	4
14	Have you been thinking about your illness?	1	2	3	4
15	Have you worried about your health in the future?	1	2	3	4
16	Have you had trouble with eating in front of other people?	1	2	3	4
17	Have you had a dry mouth?	1	2	3	4
18	Have you had problems with your sense of taste?	1	2	3	4
19	Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
20	Have you had difficulty swallowing your saliva?	1	2	3	4

21	Have you choked when swallowing?	1	2	3	4
22	Have you coughed?	1	2	3	4
23	Have you had difficulty talking?	1	2	3	4
24	Have you worried about your weight being too low?	1	2	3	4
25	Answer this question only if you lost any hair: If so, were you upset by the loss of your hair?	1	2	3	4

Part three

Clinical data extraction form for esophagogastric patients' medical chart

1	Cancer site	1.esophagous 2. gastric 3, Gastro esophageal junction
2	Started treatment	A. Yes B. No
3	If yes, for question number above what type of treatment?	A. Surgery B. Radiotherapy C. Chemotherapy
4	Treatment outcome	A, Curative B, Palliative
5	Stage	G. Stage 0 H. Stage I I. Stage II J. Stage III

		K. Stage IV L. Unknown
6	Primary Tumor size	H. Tx I. T0 J. T1 K. T2 L. T3 M. T4 N. Unknown
7	Regional lymph node	H. Nx I. N0 J. N1 K. N2 L. N3 M. N4 N. Unknown
8	Distant metastasis	E. Mx F. M0 G. M1 H. Unknown

Annex 3

3.1 የተሳታፊዎች መረጃ ቅፅ

መግቢያ

ጤና ይስጥልኝ ስሜ .....የተባልኩ ዛሬ እዚህ የተገኘሁት በአዲስ አበባ ዩኒቨርሲቲ የህብረተሰብ ጤና ተማሪ የሆነችው ጥናት እያደረገች ሲሆን ጥናቱም የማስትርስ ዲግሪ ለማግኘት የሚያስችላትን በመወከል ሲሆን ጥናቱም የ EORTC QLQ-CR 29 EORTC እና QLQ OG-25 የአማርኛ ትርጓሜ ተገቢነት እና ተአማኒነት በትልቁ አንጀት በምግብ ቱቦ እና በ ጨጓራ ካንሰር ባለባቸው ላይ የሚደረግ ጥናት ነዉ።።

አላማ፡- የ EORTC QLQ CR-29 እና QLQ-OG 25 የአማርኛ ትርጓሜ ተገቢነት እና ተአማኒነት በትልቁ አንጀት በምግብ ቱቦ እና በ ጨጓራ ካንሰርያለባቸውን ማጥናት

ቅደም ተከተል፡- የስምምነት ወረቀቱን ከፈረሙ በኋላ የተዋቀሩና አግባብ ያላቸውን ጥያቄዎች መረጃ ሰብሳቢው ይጠይቆታል ምላሽዎም ወረቀቱ ላይ ይሰፍራል መጠየቁም ቢበዛ 25 ደቂቃ ይወስዳል።።

ለተጠያቂው የሚሰጠው ጥቅም፡ ተጠያቂው ቀጥታ የሚያገኘው ጥቅም የለም ግን ተአማኒነትያለዉመጠይቅ ለማግኘት ይረዳል።።

የሚያስከትለው ጉዳት፡- መረጃ ሰብሳቢው ሲጠይቆት ምቻት ላይሰማዎ ይችላል ግን የሶ ተሳትፎ በጣም ይጠቅመናል።።

ተሳትፎዎፈቃደኝነትላይየተመሰረተነዉ፡- ለመሳተፍም ሆነ ላለመሳተፍ ሙሉ መብት አሎት፣ መጠየቁን ጀምረው ከመሀል የማቆምም ሆነ ያልፈለጉትን ጥያቄ ያለመመለስ ሙሉ መብት አሎት።።

ይህ የሚሰጡን ግላዊ መረጃ ሚስጥራዊነቱ የተጠበቀ ነው ።። ይህ መረጃ በኮምፒውተር በሚስጥር ከተመዘገበ በኃላ ስምዎት አይጠቀስም እናም በምንም አይት መንገድ ሊታወቅ አይችልም።። በኮምፒውተር ውስጥ ያለው መረጃ በሚስጥር ኮድ ታስሮ ይቀመጣል።።የሚሰጡን ሁሉም መረጃ ከተባለለት አላማ ውጪ አይውልም።።

ሰለምርምሩተጨማሪመረጃከፈለጉ ከታች የተቀሰዉን ሰዉ ማናገር ይችላሉ።።

የጥናት አድራጊዋ ስም፡- ሊዲያ ገነነ

ስልክ ቁጥር፡- +251912665940

3.2 የስምምነት ቅፅ

የጥናቱ አላማ ተረድቻለሁ። ከላይ የጥናቱ አላማ፣ ጥቅሙ ፣ ጉዳቱ፣ እንዲሁም ሚስጥራዊነቱ በሚገባኝ እና በምረዳው ቋንቋ ተገለፆልኛል፡፡ በጥናቱ ላይ ያለመሳተፍም ሆነ ከጀመርኩ በኃላ በፈለኩት ጊዜ አቋርጬ የመሄድ ሙሉ መብት አለኝ፡፡የጠየኩት ጥያቄ ሁሉ ተመልሶልኛል። በዚህ ጥናት ላይ ተሳትፎዬ ፈፅሞ በፍላጐት ላይ የተመሰረተ ነው ።

የምላሽ ሰጪ

ፊርማ_____ ቀን _____

የጠያቂው

ስም _____ ቀን _____

የመጠይቅ መለያ ቁጥር_____

የጠየቁበት ቀን _____ የተጀመረበት ሰአት_____ ያለቀበት ሰአት_____

Annex 4

4.1 Questionnaire in Amharic

	የተጠያቂው አጠቃላይ ማህበራዊ-ነክ መረጃዎች	
ነ	ዕድሜ	_____ አመት
2	ፆታ	ሀ/ ወንድ ለ/ ሴት
3	የትምህርት ደረጃ	ሀ/ አልተማርኩም ለ/ ማንብብ መፃፍ እችላለሁ ሐ/አንደኛ ደረጃ ያጠናከኩ መ/ ሁለተኛ ደረጃ ያጠናከኩ ሠ/ ኮሌጅ እና ከዚያ በላይ
4	ስራ	ሀ.ገበሬ ለ/ተቀጣሪ ሐ/ የቤት እመቤት/ስራ የሌለው መ/ ጦረተኛ ሠ/ ተማሪ ረ/ነጋዴ/ ሰ/ ሌላ(ግለፅ)----------
5	የመኖሪያ ቦታ	ሀ/ አዲስ አበባ ለ/ ከአዲስ አበባ ውጪ(ግለፅ)----------
6	6 የጋብቻ ሁኔታ	ሀ/በትዳር ላይ ያሉ

		ለ/ ያላገባች ሐ/ የፈታች/ታ መ/ባልዋ ወይም ሚስቱ የሞተችበት/ባት ሰ/ ሌላ(ግለፅ)----------

EORTC QLQ-C30 (እትም 3)

እርስዎንና ጤንነትዎን በተመለከተ የተወሰኑ ነገሮችን ለማወቅ እንፈልጋለን። እባክዎትን የሚከተሉትን ጥያቄዎች በሙሉ እርስዎ ትክክለኛ ነው ብለው ያመኑበትን በማክበብ ይመልሱ። «ትክክለኛ» መልስ ወይም «የተሳሳተ» መልስ የሚባል የለም። የሚሰጡት መረጃ ሁሉ ምስጢራዊነቱ በደንብ የተጠበቀ ይሆናል።

እባክዎን የእርስዎን የአባትዎንና የአያትዎን የስም መጀመሪያ ፊደል ይጻፉ፡- የተወለዱበት ዕለት (ቀን፣ ወር፣ ዓም)፡-

የዛሬው ዕለት (ቀን ፣ወር፣ ዓም)፡-

		በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
1	እንደ ከባድ ዘንቢል ወይም ሻንጣ መሸከም የመሳሰሉ ጉልበት የሚጠይቁ እንቅስቃሴዎችን ለማድረግ ችግር አለብዎት?	1	2	3	4
2.	ረዥም የእግር ጉዞ ለማድረግ ችግር አለብዎ?	1	2	3	4
3.	ከቤትዎ ውጭ አጭር የእግር ጎዞ ለማድረግ ችግር አለብዎ?	1	2	3	4
4.	በህመምዎ የተነሳ በቀን አልጋ ላይ ወይም ወንበር ላይ ሆነው ረዘም ላለ ሰዓት ያሳልፋሉ?	1	2	3	4

5.	ሲመገቡ፣ ሲለብሱ፣ ሲታጠቡ ወይም ሽንት ቤት ሲጠቀሙ እገዛ ያስፈልግዎታል?	1	2	3	4

	ባለፈው ሳምንት ውስጥ፡-	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
6.	ስራዎትን ወይንም የዕለት ተለት እንቅስቃሴዎትን ለማከናወን ተገድበው ነበር?	1	2	3	4
7	በትርፍ ጊዜ የሚከናወኑ ስራዎችን ወይንም ሌሎች የመዝናኛ ጊዜዎችን ለማሳለፍ ገድበዎት ነበር?	1	2	3	4
8.	ሲተነፍሱ የትንፋሽ ማጠር አጋጥሞት ነበር?	1	2	3	4
9.	የህመም ስሜት ነበረብዎ?	1	2	3	4
10.	ከወትሮው የተለየ ዕረፍት አስፈልጎዎት ነበር?	1	2	3	4
11.	የዕንቅልፍ ችግር ነበረብዎ?	1	2	3	4
12.	አቅም ያንስዎት ነበር?	1	2	3	4
13.	የምግብ ፍላጎትዎ ቀንሷል?	1	2	3	4
14.	የማቅለሽለሽ ስሜት ነበረብዎ?	1	2	3	4
15.	አስመልሶዎት ነበር?	1	2	3	4
16.	የሰገራ ድርቀት ነበረብዎ?	1	2	3	4

ባለፈው ሳምንት ውስጥ፡-		በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
17.	ተቅማጥ ነበረብዎ?	1	2	3	4

18.	የድካም ስሜት ነበረዎ?	1	2	3	4
19.	ህመሙ የዕለት ተዕለት እንቅስቃሴዎትን ያውክብዎ ነበር?	1	2	3	4
20	አንድ አንድ ነገሮችን ትኩረት ሰጥተው ለመስራት ያውክዎት ነበር (ለምሳሌ፤ጋዜጣ ለማንበብ፣ ራዲዮ ለማዳመጥ)?	1	2	3	4
21.	የውጥረት ስሜት ነበረብዎ?	1	2	3	4
22.	የመጨነቅ ስሜት ነበረብዎ?	1	2	3	4
23.	የመነጫነጭ ስሜት ነበረብዎ?	1	2	3	4
24.	የመደበር ስሜት ነበረብዎ?	1	2	3	4
25.	ነገሮችን የማስታወስ ችግር ነበረብዎ?	1	2	3	4
26.	አካላዊ ሁኔታዎ ወይም የሚከታተሉት ህክምና በቤተሰባዊ ህይወትዎ ላይ ያሳደረው ተጽዕኖ ነበር?	1	2	3	4
27.	የጤናዎ ሁኔታ ወይም የሚከታተሉት ህክምና በማህበራዊ ሕይወትዎ በሚደርጉት	1	2	3	4
28	እንቅስቃሴዎ ላይ ያሳደረው ተጽዕኖ ነበር?	1	2	3	4

ለሚከተሉት ጥያቄዎች ከ 1-7 ካሉት ቁጥሮች ውስጥ እርስዎን በደንብ የሚገልጽዎን አንዱን ቁጥር ያክብቡ

29. በአጠቃላይ ባለፈው ሳምንት የነበረዎን የጤንነት ሁኔታ እንዴት ይመዝኑታል?

1	2	3	4	5	6	7
በጣም መጥፎ						እጅግ በጣም ጥሩ

30. በአጠቃላይ ባለፈው ሳምንት የነበረዎን የኑሮ ሁኔታ ጥራት እንዴት ይመዝኑታል?

1	2	3	4	5	6	7
በጣም						እጅግ በጣም

መጥፎ						ጥሩ

EORTC QLQ – CR29

ሕመምተኞች አንዳንድ ግዜ ቀጥሎ የተዘረዘሩት የሕመም ምልክቶች ወይም ችግሮች እንዳሉባቸው ይገልፃሉ። እርስዎ ባለፈው አንድ ሳምንት ውስጥ እነዚህ የሕመም ምልክቶች ወይም ችግሮች ምን ያህል እንዳጋጠሙዎት ይግለፁልን። እባክዎ የሚከተሉትንጥያቄዎች በሙሉ እርስዎ ትክክለኛ ነው ብለው ያመኑበትን በማክበብ ይመልሱ።

ባለፈው ሳምንትውስጥ፡-	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
31. ቀንቀንውሃሽንትቶሎቶሎይሸኑነበር?	1	2	3	4
32. ማታማታውሃሽንትቶሎቶሎይሸኑነበር?	1	2	3	4
33. ሽንትያመልጥዎትወይምየማንጠባጠብችግርነበረብዎ?	1	2	3	4
34. ሽንትሲሸኑየህመምስሜትነበረብዎ?	1	2	3	4
35. የሆድህመምነበረብዎት?	1	2	3	4
36. በመቀመጫዎወይምፊንጢጣዎወይምበሬክተምዎ አካባቢየህመምስሜትነበረብዎ?	1	2	3	4
37. ሆድዎየመነፋትስሜትነበረብዎ?	1	2	3	4
38. ከደምጋርየተቀላቀለአይነምድርወጥተውነበር?	1	2	3	4
39. ከንፍጥጋርየተቀላቀለአይነምድርወጥተውነበር?	1	2	3	4
40. አፍዎይደርቅቦትነበር?	1	2	3	4
41. በወሰዱትህክምናምክንያትፀጉርዎሳስቶወይምተመልጦነበር?	1	2	3	4
42. ጣእምየመለየትችግርአጋጥሞት ነበር?	1	2	3	4

ባለፈው ሳምንትውስጥ፡-	በጭራሽ	በትንሹ	በመጠኑ	በጣም	በብዛት
43. ስለወደፊትጤንነትዎይጨነቁነበር?	1	2	3	4	
44. ስለክብደቶይጨነቁ ነበር?	1	2	3	4	
45. በሕመምዎወይምበሕክምናውምክንያትዓይንየማይስቡሰው እንደሆኑዓይነትስሜትተሰምቶዎትነበር?	1	2	3	4	
46. በህመምዎወይምበህክምናውምክንያትሴትነትዎወይምወንድነትዎ እንደቀነሰብዎትተሰምቶዎትነበር?	1	2	3	4	
47. በሰውነትዎያልረኩበትጊዜነበር?	1	2	3	4	
48. ስቶማ ባግ(ዓይነምድርከትልቁ አንጀትወደሆድመቀበያ(ኮሎስቶሚ) ወይምከትንሹአንጀት ወደሆድመቀበያ (ኢሊዮስቶሚ)) አላችሁእባኮት ትክክለኛውንመልሱን ያክብቡ?	አዎ	አይደለም			

እነዚህን ጥያቄዎች ስቶማ ባግ ያላችሁ ብቻ መልሱ፡፡ ከሌላችሁ እባካችሁ ኪታች ይቀጥሉ					
ባለፈው ሳምንትውስጥ	በጭራሽ	በትንሹ	በመጠኑ	በጣም	በብዛት
49. ከስቶማባግጋዝወይምፈሰያመልጠዎትነበር?	1	2	3	4	
50. ከስቶማባግአይነምድርየመንጠባጠብችግርነበረብዎ?	1	2	3	4	
51. ከስቶማባግአካባቢያለቆዳዎትቀለልያለህመምወይምሲነካየማመምስሜትነበረው?	1	2	3	4	

52. ስቶማባግቀንቀንቶሎቶሎይቀየርነበር?	1	2	3	4
53. ስቶማባግማታማታቶሎቶሎይቀየርነበር?	1	2	3	4
54. በስቶማዎምክንያትህፍረትተሰምቶዎትነበር?	1	2	3	4
55. ስቶማዉንበጥንቃቄለመያዝያስቸግሮትነበር?	1	2	3	4

እነዚህን ጥያቄዎች ስቶማ ባግ ከሌላችሁ ብቻ መልሱ፡፡				
ባለፈው ሳምንትውስጥ	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
49. ጋዝወይምፈስከሬክተሞያመልጥዎትነበር?	1	2	3	4
50. በድንገትአይነምድርያመልጥዎትወይምይንጠባጠብቦትነበር?	1	2	3	4
51. በፊንጢጣዎአካባቢያለውቆዳአካባቢያለቆዳዎትቀለል ያለ ህመምወይምሲነካየማመምስሜትነበረው?	1	2	3	4
52. ቀንቀንዓይነምድርቶሎቶሎይመጣብዎነበር?	1	2	3	4
53. ሌሊትሌሊትዓይነምድርቶሎቶሎይመጣብዎትነበር?	1	2	3	4
54. አይነምድርቶሎቶሎስለሚመጣቦትህፍረትተሰምቶዎትነበር?	1	2	3	4

ለወንዶች ብቻ				
ባለፉትአራትሳምንታትውስጥ፡-	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
56. ለጾታዊግንኙትፍላጐትዎምንያህልነበር?	1	2	3	4
57. በጾታዊግንኙነት ጊዜ ብልትዎያለመቆም ወይምጾታዊ ግንኙነትዎን እስኪጨርሱብልቶ ቆሞያለመቆየት ችግር ነበረበዎት?	1	2	3	4

ለሴቶች ብቻ				
ባለፉትአራትሳምንታትውስጥ፡-	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
58. ለዖታዊግንኙነትፍላጐትዎምንያህልነበር?	1	2	3	4
59. በግብረስጋግንኙነትጊዜህመምወይምምቾትማጣትነበረብዎ?	1	2	3	4

EORTC OG 25 ሕመምተኞች አንዳንድ ግዜ ቀጥሎ የተዘረዘሩት የሕመም ምልክቶች ወይም ችግሮች እንዳሉባቸው ይገልፃሉ። እርስዎ <u>ባለፈው</u> <u>አንድ ሳምንት ውስጥ</u> እነዚህ የሕመም ምልክቶች ወይም ችግሮች ምን ያህል እንዳጋጠሙዎት ይግለፁልን። እባክዎ የሚከተሉትንጥያቄዎችበሙሉ እርስዎትክክለኛነው ብለውያመኑበትንበማክበብ ይመልሱ።

ባለፈው ሳምንትውስጥ፡-	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
31. ጠጣር ምግቦችንለመውሰድይቸገሩ ነበር?	ነ	2	3	4
32. የቀጠነ ወይምለስላሳ ምግብለመመገብ ተቸግረው ነበር?	ነ	2	3	4
33. ፈሳሽ ነገሮችንለመጠጣት ይቸገሩ ነበር?	ነ	2	3	4
34. ምግብዎትንደስብሎት ለመመገብይቸገሩ ነበር?	ነ	2	3	4

35. መመገብእንደጀመሩ በጣምበቶሎየጠገቡ ይመስለዎት ነበር?	1	2	3	4
36. ምግብዎትንለመጨረስረዥምጊዜይወስድብዎትነበር?	1	2	3	4
37. ምግብሲመገቡይቸገሩ ነበር?	1	2	3	4
38. ያቃጥሎት ወይምያቅሮትነበር?	1	2	3	4
39. ሃሞት ወይምየሚኮመጥጥነገር ወደአፎ የመምጣትችግር ነበረቦ?	1	2	3	4
40. ምግብሲመገቡምቾት አይሰማዎትም ነበር?	1	2	3	4
41. ምግብሲመገቡየህመምስሜት ነበረብዎ?	1	2	3	4
42. በሆድዎበስተግራከላይአካባቢየህመም ስሜት ነበረብዎ?	1	2	3	4
43. በሆድዎበስተግራከላይአካባቢምቾት አይሰማዎትምነበር?	1	2	3	4
44. ስለህመሞ ያስቡ ነበር?	1	2	3	4
45. ስለወደፊትጤንነትዎይጨነቁ ነበር?	1	2	3	4
46. ከሌሎችሰዎች ፊት ለመመገብ ይቸገሩ ነበር?	1	2	3	4
47. አፍዎይደርቅቦት ነበር?	1	2	3	4
48. ጣእምየመለየት ችግር ነበረብዎት?	1	2	3	4
49. በሕመምዎወይምበሕክምናውምክንያት ዓይንየማይስቡ ሰው እንደሆኑዓይነትስሜት ተሰምቶዎት ነበር	1	2	3	4

ባለፈው ሳምንትውስጥ	በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
50. ምራቅ ለመዋጥይቸገሩ ነበር?	1	2	3	4
51. ሲውጡትንይልዎት ነበር?	1	2	3	4
52. ያስሉ ነበር?	1	2	3	4

53. ለማውራት ይቸገሩ ነበር?	1	2	3	4
54. ክብደቶ ትንሽ ስለሆነ ይጨነቁ ነበር?	1	2	3	4
55. ይህንንጥያቄ ፀጉርዎ ሳስቶወይምተመልጦ ከነበረብቻይመልሱ፡-ፀጉርዎበመሳሳቱ ወይምበመመለጡ ተበሳጭተውነበር?	1	2	3	4

4.2. Pre-test sample of a patient response sheet

Questionnaire number----------

	yes	No	Comment
A, difficulty			
B, confusing			
C, difficult words			
D, upsetting words			
E, How would you ask this question			

4.3. Pre-test respondents socio-demographic and clinical characteristics

Socio-Demographic characteristics of pre-test respondents in Tikur Anbessa Hospital, Addis Ababa, 2020

Variable	Category	Frequency (n=20)	Per cent (%)
Sex	Male	9	45
	Female	11	55
Educational status	No formal education	8	40
	Primary education	6	30
	Secondary education	3	15
	College and above	3	15
Occupation	Farmer	3	15
	Employed	5	25
	House wives	6	30
	Retired	1	5
	Student	2	10
	Merchant	3	15
Region	Addis Ababa	12	60
	Oromia	1	5

	Amhara	4	20
	SNNPR	2	10
	Tigray	1	5
Marital status	Married	11	55
	Single	3	15
	Divorced	5	25
	Widowed	1	5
Age, median(IQR)		45.50(10.75)	

Clinical characteristics of pre-test respondents in Tikur Anbessa Hospital, Addis Ababa, 2020

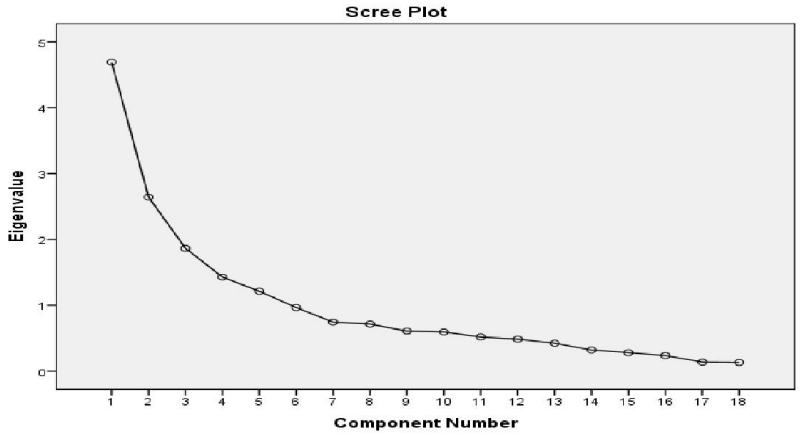
Variables	**Category**	**Frequency(n=316)**	**Per cent (%)**
Cancer site	Colon	5	25
	Rectal	5	25
	Gastric	4	20
	Esophageal	6	30
Type of treatment	Chemotherapy	10	50
	Chemotherapy and surgery	2	10
	Chemotherapy and Radiotherapy	2	10
	Chemotherapy, Surgery, and Radiotherapy	6	30
Stage	Stage I	4	20
	Stage II	2	10
	Stage III	2	10
	Stage IV	12	60
Treatment intent	Curative	5	25
	Palliative	15	75

Annex 5

5.1. EORTC CR-29 symptom and functional PCA result

5.1.1. Symptom dimension for EORTC CR-29

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.709
Bartlett's Test of Sphericity	Approx. Chi-Square	1209.784
	df	153
	Sig.	.000



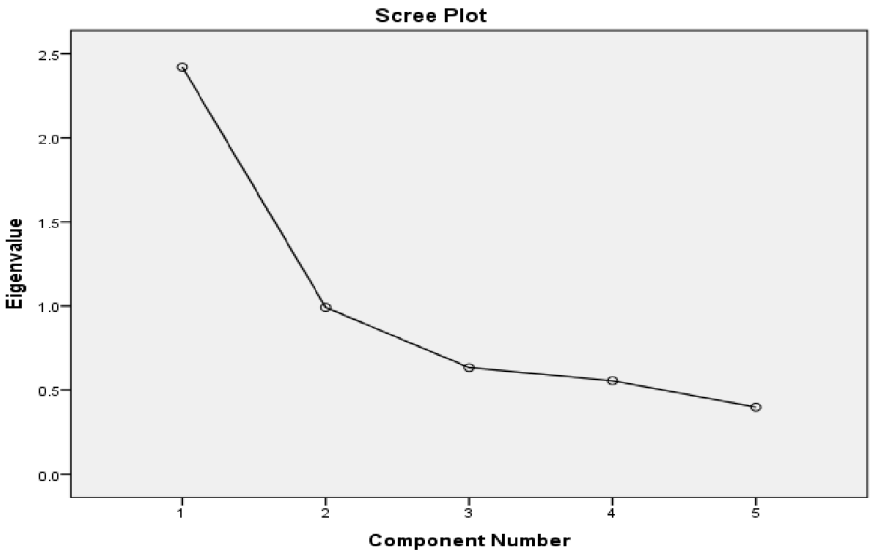
Component	Initial Eigenvalues			Randomly generated Eigenvalues Specifications for this Run: Ncases = 158, Nvars = 18, Ndatsets= 50, Percent = 95		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	4.692	26.068	26.068	4.692	1.634361	1.767697
2	2.644	14.689	40.758	2.644	1.509017	1.587658
3	1.865	10.361	51.118	1.865	1.408380	1.501563
4	1.428	7.934	59.052	1.428	1.328175	1.379057
5	1.214	6.743	65.794	1.214	1.254190	1.307380
6	.964	5.358	71.152	.964	1.185813	1.244966

Rotated component matrix for EORTC CR-29 symptom domain

Rotated Component Matrix[a]						
	Component					
	1	2	3	4	5	6
SCR31			.845			
SCR32			.903			
SCR33	.307	.312	.465	.431		
SCR34	.488			.475		
SCR35	.699				.403	
SCR36	-.371	.645				
SCR37	.826					
SCR38					.864	
SCR39	.641		.368			
SCR40		-.332	.428	.371	.336	.319
SCR41	.360		-.391	.388	.368	-.335
SCR42	.350			.462	.580	
SCRstoma49				.715		
SCRstoma50				.782		.336
SCRstoma51	.394	.519		.363		
SCRstoma52		.781				
SCRstoma53		.808				
SCRstoma54		.337				.797
Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.						
a. Rotation converged in 10 iterations.						

5.1.2. Functional dimension for EORTC 29

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.702
Bartlett's Test of Sphericity	Approx. Chi-Square	168.196
	df	10
	Sig.	.000



Total Variance Explained						
Component	Initial Eigenvalues			Randomly generated Eigenvalues Specifications for this Run: Ncases = 158, Nvars = 7 Ndatsets= 50, Percent = 95		
	Total	% of Variance	Cumulative %	root	means	percentile
1	2.421	48.420	48.420	1	1.312742	1.405649
2	.991	19.825	68.245	2	1.179438	1.250777

Rotated component matrix for EORTC CR-29 functional domain

Rotated Component Matrix[a]		
	Component	
	1	2
SCR43		.828
SCR44		.819
SCR45	.831	
SCR46	.590	.507
SCR47	.834	
Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.		
a. Rotation converged in 3 iterations.		

5.1.3. EORTC OG-25 scales

Eating scale

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.584
Bartlett's Test of Sphericity	Approx. Chi-Square	98.789
	df	3
	Sig.	.000

Dysphagia scale

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.628
Bartlett's Test of Sphericity	Approx. Chi-Square	68.380
	df	6
	Sig.	.000

Reflux scale

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.500
Bartlett's Test of Sphericity	Approx. Chi-Square	53.642
	df	1
	Sig.	.000

Odynophagia scale

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.500
Bartlett's Test of Sphericity	Approx. Chi-Square	9.340
	df	1
	Sig.	.002

Pain and Discomfort scale

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.500
Bartlett's Test of	Approx. Chi-Square	45.159

Sphericity	df	1
	Sig.	.000

Anxiety scale

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.500
Bartlett's Test of Sphericity	Approx. Chi-Square	41.263
	df	1
	Sig.	.000

Component matrix for EORTC QLQ OG-25 tool

Component matrix		
Scales	Items	Component one
Dysphagia	Item 31	0.608
	Item 32	0.873
	Item 33	0.845
Eating	Item 34	0.705
	Item 35	0.618
	Item 36	0.636
	Item 37	0,745
Reflux	Item 38	0.878
	Item 39	0.878
Odynophagia	Item 40	0.788
	Item 41	0.788
Pain and discomfort	Item 42	0.867
	Item 43	0.867
Anxiety	Item 44	0.861
	Item 45	0.861

Annex 6

Correlation between the core questionnaire and the tools

Correlation between the EORTC QLQ-CR29 and functional subscales of the EORTC QLQ-C30, Addis Ababa, Ethiopia, 2020

	PF	RF	EF	CF	SF	QOL
Body image	0.43**	0.25**	0.57**	0.24**	0.30**	-0.04
Anxiety	0.30**	0.28**	0.32**	-0.11	0.24**	0.06
Weight	0.30**	0.22**	0.31**	0.20*	0.32**	-0.08
Sexual interest (men)	-0.26*	-0.22*	-0.09	0.20	-0.26*	0.01
Sexual interest (women)	-0.31**	-0.23*	-0.05	-0.20	-0.09	0.11
Urinary frequency	-0.02	-0.01	-0.21**	0.10	-0.21**	0.11
Blood and mucus in stool	-0.14	-0.05	-0.16*	-0.40**	-0.15	0.24**
Stool frequency	-0.22**	-0.30**	-0.40**	0.07	-0.15	-0.01
Urinary incontinence	-0.24**	-0.23**	-0.23**	-0.22**	-0.42**	0.14
Dysuria	-0.28**	-0.31**	-0.40**	-0.20**	-0.32**	-0.10
Abdominal pain	-0.13	-0.08	-0.08	-0.14	-0.02	0.07
Buttock pain	-0.12	-0.17*	-0.07	0.15*	-0.14	-0.19*
Bloating	-0.27**	-0.22**	-0.34**	-0.22**	-0.17*	0.15*
Dry mouth	-0.28**	-0.10	-0.23**	-0.27**	-0.19*	0.24**
Hair loss	-0.33**	-0.27**	-0.08	-0.38**	-0.20*	0.07
Taste	-0.29**	-0.30**	-0.08	-0.34**	-0.19*	-0.02
Flatulence	-0.42**	-0.29**	-0.10	-0.46**	-0.30**	0.11
Fecal incontinence	-0.30**	-0.41**	-0.34**	-0.38**	-0.35**	0.01
Sore skin	-0.21**	-0.37**	-0.35**	-0.11	-0.26**	0.08
Embarrassment	-0.12	-0.15	-0.33**	0.05	-0.10	0.08
Stoma care problems	-0.10	-0.03	-0.19*	0.11	-0.13	-0.07
Impotence	0.03	0.13	-0.03	-0.03	0.01	0.18*
Dyspareunia	0.01	0.02	0.03	-0.01	-0.05	-0.16*

QOL= quality of life, PF= Physical functioning, RF= Role functioning, EF= Emotional functioning, CF= Cognitive functioning, SF= Social functioning, * Correlation is significant at the 0.05 level, **. Correlation is significant at the 0.01 level

Correlation between the EORTC QLQ-CR29 and symptom subscales of the EORTC QLQ-C30, Addis Ababa, Ethiopia, 2020

	FAT	NVO	PAI	DYS	INS	AP T	CON	DIA	FIP
Body image	-0.41**	-0.27**	-0.30**	-0.41**	-0.32**	-0.26**	-0.34**	-0.24**	-0.31**
Anxiety	-0.11	-0.04	-0.01	-0.22**	-0.17*	-0.02	0.01	-0.01	-0.29**
Weight	-0.17*	-0.10	-0.12	-0.19*	-0.17*	-0.19*	-0.01	0.02	-0.22**
Sexual interest men	-0.10	-0.13	0.04	0.01	0.04	-0.05	-0.19	-0.18	0.27*
Sexual interest (women)	0.10	-0.13	0.23*	0.05	0.01	0.11	0.12	-0.18	0.15
Urinary frequency	0.17*	-0.02	0.04	0.00	0.05	0.01	0.16*	0.12	0.09
Blood and mucus in stool	0.23**	0.26**	0.38**	0.07	0.15*	0.18*	0.15*	0.15	-0.01
Stool frequency	0.41**	0.14	0.07	0.04	0.07	0.16*	0.35**	0.33**	0.21**
Urinary incontinence	0.28**	0.16*	0.18*	0.32**	0.20**	0.14	0.11	0.15*	0.30**
Dysuria	0.33**	0.30**	0.25**	0.44**	0.34**	0.45**	0.28**	0.17*	0.27**
Abdominal pain	0.02	0.38**	0.34**	0.15*	0.43**	0.23**	0.26**	0.19*	-0.02
Buttock pain	0.02	0.07	0.01	-0.13	0.01	0.19*	0.01	0.03	0.17*
Bloating	0.31**	0.18*	0.23**	0.36**	0.39**	0.19*	0.38**	0.20**	0.09
Dry mouth	0.07	0.19*	0.32**	0.20**	0.14	0.02	0.14	-0.20*	0.14
Hair loss	0.13	0.32**	0.27**	0.19*	0.31**	0.36**	0.04	-0.03	.032**
Taste	0.10	0.38**	0.44**	0.24**	0.35**	0.32**	-0.01	0.02	0.28**
Flatulence	0.08	0.37**	0.13	0.21**	0.17*	0.34**	-0.06	-0.17*	0.23**
Fecal incontinence	0.17*	0.28**	0.13	0.37**	0.17*	0.31**	0.01	0-.04	0.34**
Sore skin	0.27**	0.26**	0.05	0.21**	0.28**	0.36**	0.25**	0.20**	0.25**
Embarrassment	.220**	.056	.067	.154	.089	.082	.246**	.241**	-.047
Stoma care problems	-0.05	-0.03	-0.15	0.12	0.01	-0.08	-0.09	0.01	-0.01
Impotence	0.06	-0.10	-0.11	-0.04	-0.10	-0.16*	0.07	-0.02	-0.21**
Dyspareunia	-0.05	0.01	0.12	0.13	0.08	0.12	-0.05	0.03	0.18*

FAT= Fatigue, NVO= Nausea/vomiting, PAI= Pain, DYS= Dyspnea, INS= Insomnia, APL= Appetite loss, CON= Constipation, DIA= Diarrhea, FIP= Financial problems, * Correlation is significant at the 0.05 level, **. Correlation is significant at the 0.01 level

Correlation between the EORTC QLQ-OG25 and symptom subscales of the EORTC QLQ-C30, Addis Ababa, Ethiopia, 2020

EORTC-OG 25 scales and items	FAT	NVO	PAI	DYS	INS	AP T	CON	DIA	FIP
Dysphagia	0.09	0.3**	0.29**	0.35**	0.16*	0.24**	-0.02	0.29**	0.36**
Eating	0.54**	0.35**	0.55**	0.40**	0.45**	0.49**	0.34**	0.27**	0.23**
Reflux	0.53**	0.48**	0.50**	0.22**	0.48**	0.46**	0.47**	0.37**	0.24**
Odynophagia	0.40**	0.40**	0.40**	0.34**	0.24**	0.35**	0.21**	0.19*	0.31**
Pain and discomfort	0.24**	0.13	0.20*	0.29**	0.04	0.12	0.16*	-0.10	0.12
Anxiety	0.38**	0.23**	0.35**	0.4**	0.36**	0.31**	0.26**	0.11	0.10
Eating with others	0.26**	0.31**	0.29**	0.22**	0.40**	0.35**	0.27**	0.27**	0.20*
Dry mouth	0.35**	0.24**	0.38**	0.4**	0.39**	0.29**	0.33**	0.18*	0.35**
Trouble with taste	-0.11	0.18*	-0.04	0.12	0.11	0.07	-0.19*	0.34**	0.14
Body image	0.41**	0.45**	0.45**	0.29**	0.48**	0.35**	0.37**	0.40**	0.37**
Trouble swallowing saliva	0.07	0.40**	0.26**	0.19*	0.28**	0.18*	-0.04	0.34**	0.28**
Choked when swallowing	0.35**	0.42**	0.36**	0.35**	0.29**	0.28**	0.13	0.24**	0.42**
Trouble with coughing	0.36**	0.34**	0.47**	0.47**	0.48**	0.33**	0.22**	0.18*	0.44**
Trouble talking	0.62**	.30**	0.52**	0.26**	0.47**	0.33**	0.40**	0.27**	0.17*
Weight loss	0.24**	0.29**	0.36**	0.29**	0.32**	0.3**	0.21**	0.33**	0.33**
Hair loss	0.20*	0.18*	0.13	0.07	0.16	0.22**	0.18*	0.09	-0.05

FAT= Fatigue, NVO= Nausea/vomiting, PAI= Pain, DYS= Dyspnea, INS= Insomnia, APL= Appetite loss, CON= Constipation, DIA= Diarrhea, FIP= Financial problems, * Correlation is significant at the 0.05 level, **. Correlation is significant at the 0.01 level

Annex 7

Clinical validity

Known group comparisons: scales and items in the EORTC QLQ CR29 for clinically distinct groups, Addis Ababa, Ethiopia, 2020

CR-29	Treatment mean rank value			Presence of stoma			Physical function		
	Curative N=38	Palliative N=138	P value	Yes N=60	No N=98	P value	Worse N=79	Better N=79	p-value
BI	76.03	80.60	0.84	79.01	79.80	0.92	66.99	92.01	0.00
AN	78.25	79.90	1.00	65.95	87.80	0.002	74.37	84.63	0.13
WET	76.22	80.54	0.99	80.73	78.74	0.78	73.11	85.89	0.07
SXM	34.65	44.33	0.10	47.27	38.70	0.87	16.67	45.67	0.25
SXW	36.28	38.54	0.64	39.18	37.30	0.49	43.13	31.81	0.07
UFR	79.53	79.49	1.00	89.78	73.21	0.02	80.06	78.94	0.87
BM	82.18	78.65	0.99	69.50	85.6	0.02	84.40	74.60	0.15
STF	78.59	79.79	0.98	86.78	75.04	0.11	83.23	75.77	0.30
URI	82.92	78.42	0.97	82.53	33.33	0.49	82.09	76.91	0.45
DY S	87.25	77.05	0.80	77.85	80.51	0.70	89.18	69.82	0.00
ABP	79.08	79.63	1.00	69.20	85.81	0.02	88.94	70.06	0.01
BTP	74.57	81.06	0.86	84.89	76.20	0.23	82.50	76.50	0.39
BLO	76.63	80.41	1.00	75.12	82.18	0.30	88.21	70.79	0.01
DRM	75.83	80.66	0.87	80.37	78.97	0.84	91.20	67.80	0.00
HRL	87.16	77.08	0.60	66.35	87.55	0.003	93.04	65.96	0.00
TAT	75.39	80.80	0.99	68.37	86.32	0.01	90.32	68.68	0.00
FLU	76.59	80.42	0.99	89.68	73.27	0.02	95.54	63.46	0.00
FEI	74.55	81.07	1.00	88.01	74.29	0.051	87.53	71.47	0.02
SOS	77.55	80.12	0.96	80.12	79.12	0.89	84.40	74.60	0.16
EMB	83.78	78.15	0.96	108.25	61.90	0.00	82.70	76.30	0.34
SCR	34.19	29.48	0.472	NA	NA	NA	35.05	25.95	0.03
IMP	35.58	44.04	0.16	48.77	37.75	0.16	45.12	39.37	0.12
DYS	43.47	36.27	0.64	34.91	39.84	0.37	35.57	40.93	0.23

Body image= BI, Anxiety= AN, Weight=WET, Sexual interest (men)=SXM, Sexual interest (women)= SXF, Urinary frequency= UFR, Blood and mucus in stool=BM, Stool frequency=STF, Urinary incontinence=URI,

Dysuria=DYS, Abdominal pain= ABP, Buttock pain=BTP, Bloating=BLO, Dry mouth=DRM, Hair loss=HRL, Taste=TAT, Flatulence=FLU, Fecal incontinence=FEI, Sore skin =SOS, Embarrassment=EMB, stoma care problem=SCR Impotence=IMP, Dyspareunia=DYP, NA= not applicable

Annex 8

Permission letter to use the tools

From: no-reply@eortc.be

To: lidyagenene@gmail.com

Sent: Thu, 21 Nov, 01:04

Subject: Your request for an EORTC-questionnaire Request ID: 64619

Dear Lidya Abebe,

Thank you for registering on the EORTC Quality of Life Group website. Your registration to obtain permission to use our tools has been approved

From: anne.stone@eortc.org

To: lidyagenene@gmail.com

Dear Lidya,

Many thanks for your email, and for these reports! This is great news. Since patients had no problems understanding the translation of CR29 and OG25 (Amharic), please find attached the final documents which you may now use!

Annex 9

ASSURANCE OF PRINCIPAL INVESTIGATOR

I, the undersigned MPH student declare that this thesis is my original work in fulfillment of requirement for the master of public health in Epidemiology and Biostatistics.

Name of the student: Lidya Genene

Date._____

Signature_____

Approval of the primary Advisor

This thesis work has been submitted with our approval as the university advisor.

Name of the primary advisor: Dr. Adamu Addissie (MD, PhD)

Date._____ Signature _____