ORIGINAL RESEARCH

Validity and Reliability of the Amharic Version of EORTC-QLQ-CR29 Among Colorectal Cancer Patients in Ethiopia

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Background: The European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire (EORTC-QLQ) developed to assess quality of life among colorectal cancer patients has not been translated into a local language or validated in the Ethiopian context. Therefore, this study aimed to examine the psychometric properties of the EORTC-QLQ-CR29 tool in Ethiopia among colorectal cancer patients.

Methods: A cross-sectional study was conducted in a major referral hospital in Addis Ababa, Ethiopia, from March to May, 2020. A total of 158 colorectal cancer patients were included. The validity of the tool was assessed using Multitrait Scale Analysis, Mann–Whitney test and Pearson correlation coefficient. The internal consistency was examined using Cronbach's alpha.

Results: Among the participants, 52.2% were men, with a median age of 46 years (IQR = 17.7 years). The item-total correlation alpha values ranged from 0.47 to 0.91. Multitrait Scale Analysis demonstrated convergent and divergent validity of the tool, except for the Blood and Mucus in Stool scale. All item correlations within their scales were greater than 0.4, except for the Blood and Mucus in Stool scale. The values of correlation coefficients between all items and their own domain were higher than other domains, except for the Blood and Mucus in Stool scale. The correlation between the core questionnaire and the colorectal tool ranged from −0.45 to 0.58. The tool showed a significant difference between stoma and non-stoma patients and between patients who had good physical function and those who did not.

Conclusion: The Amharic version of the EORTC-QLQ-CR29 tool can be used to assess the health-related quality of life in Ethiopian colorectal cancer patients.

Keywords: validity, EORTC-QLQ, colorectal cancer, Ethiopia

Introduction

Colorectal cancer is the third leading cause of cancer cases worldwide. In 2018, there were more than 1.8 million new cases and 881,000 deaths from colorectal cancer.[1] The incidence of colorectal cancer is higher in high-income countries, but the mortality is higher in low- and middle-income countries. In Eastern Africa, colorectal cancer was the fourth most frequently diagnosed cancer type.[2] In Ethiopia, the second most populous country in sub-Saharan Africa, colorectal cancer is the most common cancer diagnosis in males and it ranks fourth in females.[3] It is also responsible for 11.2% of cancer-related deaths in males and 4.8% of cancer-related deaths in females in Ethiopia.

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Gastrointestinal cancer patients have been reported to suffer from problems that emerged as a consequence of both the disease and the treatments, which negatively affect their quality of life.[4] For instance, colorectal cancer symptoms and its treatments have several adverse effects and toxicity, which affect quality of life.[5,6] Colorectal cancer patients have significantly lower physical, role, cognitive and social function compared to the general public. Moreover, they have a higher frequency of constipation, diarrhoea and financial difficulties.[7–9] Thus, further research on health-related quality of life is recommended to guide decision making in treatment choice.[10]

The World Health Organization (WHO) defines "quality of life" as a broad concept that depends on a person's physical health, psychological state, level of freedom, social relationships, and personal beliefs.[11] Cancer treatments have started incorporating quality of life as an end point.[12] Thus, different sensitive, reliable and validated tools are available to assess quality of life among cancer patients. Frequently used tools are the core EORTC-QLQ, the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System, the Rotterdam Symptom Checklist (RSCL), and the Symptom Distress Scale (SDS).[13] Of these, the core EORTC-QLQ has been recommended to be used when the aim of the study is to assess disease-specific symptoms.[14,15] To complement the core EORTC-QLQ, different disease-specific modules have been developed, and the EORTC-QLQ for colorectal cancer patients (EORTC-QLQ-CR29) is one of these tools. This tool has been developed to be used alongside the core tool in colorectal cancer patients. This disease-specific tool has been validated in different countries such as Spain, Taiwan, Korea and China.[16–19] Even though the Ethiopian Federal Ministry of Health has developed a strategy to assess and treat distressing symptoms in cancer patients,[20] there are no validated tools to assess quality of life among colorectal cancer patients. Therefore, this study intended to examine the reliability and construct validity of EORTC-QLQ-CR29 tool among Ethiopian colorectal cancer patients.

Materials and Methods
Study Design, Area and Participants
A cross-sectional study was carried out at Tikur Anbessa Specialized Hospital (TASH) from March to May, 2020 in colorectal cancer patients. TASH is the largest referral and teaching hospital in Ethiopia, serving as the only radiotherapy centre in the country. In this oncology centre, there are two radiotherapy machines, 36 inpatient beds and 12 outpatient chemotherapy beds. There are also six clinical oncologists, who provide the oncology services.[21]

The sample size was calculated based on the recommendations of 5 to 10 participants /item for checking factor structure and validity of items given for scaling analysis.[22,23] The tool has 29 items; thus, a minimum sample size of 145 participant is required. However, within the study period, 160 participants were approached and 158 of them participated in the study. Since Amharic is the official working language of Ethiopia and is spoken by millions of Ethiopians as a second language, 158 pathologically-confirmed Amharic speaking colorectal cancer patients aged 18 years or older were included while being treated at the TASH oncology department.

Instrument
EORTC-QLQ-CR29 is a 29-item module developed to complement the core EORTC-QLQ. It comprises 19 single items and four scales to assess urinary frequency, blood or mucus in the stool, stool frequency, body image, and other problems faced by patients. The tool scales are generally classified as functional and symptom scales.[24] Since most patients do not have formal education, it may be difficult to use a self-administered questionnaire. Therefore, patients' socio-demographic, clinical characteristics, and quality of life data were collected using an interview-administered questionnaire.

The EORTC-QLQ-CR29 tool was translated into Amharic according to the EORTC translation guidelines.[25] Two native Amharic speakers independently translated the instrument from English to Amharic. These versions were discussed in the research group and a consensus was reached. After that, two proficient English speakers translated the Amharic version back to English. Then, it was sent to the EORTC translation group for reviewing and proofreading. After receiving the comments from the EORTC translation group, a pilot was conducted. The study was conducted to identify difficult, confusing and upsetting questions. None of the questions were found to be difficult, confusing or upsetting for the participants. Based on the recommendations from the pilot study,[25] ten colorectal cancer patients took part in the pilot, and these participants were excluded from the actual study.

After the completion of the pilot study, the data collection commenced. The data was collected by two nurses who have bachelor's degrees and work in the oncology centre.

Training on how to collect the data was given to the data collectors by the principal investigator for three days, focusing on the purpose of the study, contents of the questionnaire, and how to approach and get consent from patients. The principal investigator supervised the data collection process every other day to monitor the data collection procedure. Patients were approached in the waiting room while waiting for their turns. To ensure confidentiality and anonymity of the participants, code was used in the questionnaire instead of respondents' names.

Data Analysis

Descriptive statistics were used to assess the frequency distributions of socio-demographic characteristics and clinical data. Numbers and percentages were used for categorical variables and median, and interquartile range were used for continuous variables. The reliability was assessed using Cronbach's alpha. A value of Cronbach's alpha of 0.70 or greater was considered to be adequate.[23]

Convergent validity, the extent to which two measures are related to the same construct, was determined by employing Multitrait scaling analysis. Multitrait scaling analysis focuses on items as the unit of analysis.[23]

Known-groups validity was checked using the Mann-Whitney test to see whether the tool is able to detect differences between groups. The known groups that were used for comparison were treatment intent, physical function, and presence of stoma.[24] Based on the median value of the physical scale of the core EORTC-QLQ, patients were classified as having better or worse physical function. Those patients with a median score of $\geq$ 43.3 for the physical scale were considered to have better physical function whereas those below 43.3 were considered to have worse physical function.[26]

The correlations between the items of the colorectal cancer and core tools scales were determined using Pearson Correlation Coefficient. All scales and items were transformed into a 0–100 score as per the EORTC-QLQ scoring manual.[27] Statistical analyses were performed using SPSS, version 21.

Results

Socio-Demographic Characteristics of Respondents

A total of 158 participants were included in this study, with a median age of 46 (IQR =17.7). About 50 (32.3%) study participants had no formal education and were employed (32.3%) while 45 (28.5%) respondents had attended college. As presented in Table 1, the majority of the study participants were men (52.5%), married (63.3%), and residents of Addis (64.4%).

Clinical Characteristics of Respondents

85 of the respondents (53.8%) were treated for rectal cancer. Seventy-eight respondents (49.4%) were being treated with chemotherapy alone. About 120 respondents (75.9%) were treated with palliative intent. The majority of respondents (72.2%) were stage-four cancer patients (Table 2).

Reliability of EORTC-QLQ-CR29

The reliability of the tool was examined based on the value of Cronbach's alpha coefficients (alpha $\geq$ 0.70). As presented in Table 3, all of the scales had an alpha value of greater than or equal to 0.7, except for the Mucus and Blood in Stool scale (0.47). Urinary Frequency had the highest alpha value (0.91), followed by Stool Frequency (0.85).

Construct Validity

Convergent and Divergent Validity Results of Multitrait Scaling Analysis for EORTC-QLQ-CR29

Convergent and divergent validity were assessed in terms of item-own scale and item-other scale correlation, respectively. The item-own scale correlation was over 0.4 for all scales. Similarly, the item-own correlation for all scales was higher than the item-other scale correlation. As seen in Table 4, except for the Blood and Mucus in Stool scale, all scales have an item-own correlation of above 0.4 and an item-other scale correlation below the item-own scale correlation of 0.4.

The Correlation Between the Core EORTC-QLQ and CR29 Scales

The correlation between the core EORTC-QLQ and CR29 scales ranged from −0.45 to 0.58. The highest correlation was seen between the Body Image scale from the colorectal tool and the Emotional scale from the core questionnaire. The highest negative correlation was observed between Flatulence and Cognitive Function (r = −0.45). Most of the correlations between the core EORTC-QLQ and CR29 were below 0.4 (Table 5).

Known-Groups Validity of EORTC-QLQ-CR29

To assess the known-groups validity of the tool, comparisons of scores of multi-item scales and single items of

Table 1 Socio-Demographic Characteristics of Respondents at Tikur Anbessa Specialized Hospital, Addis Ababa, 2020

Variable	Category	Frequency (n = 158)	Percent (%)
Sex	Men	83	52.5
	Women	75	47.5
Educational status	No formal education	51	32.3
	Primary education	35	22.2
	Secondary education	27	17.1
	College and above	45	28.5
Occupation	Farmer	11	7
	Employed	51	32.3
	Housewife	51	32.3
	Retired	11	7
	Student	19	12
	Merchant	15	9.5
Region	Addis Ababa	102	64.6
	Oromia	27	17.1
	Amhara	17	10.8
	Others*	12	7.5
Marital status	Married	100	63.3
	Single	28	17.7
	Divorced	13	8.2
	Widowed	17	10.8
Age	18–45	132	41.8
	46–65	170	53.8
	>65	14	4.4

Notes: *Others = Tigray; Southern Nations, Nationalities and Peoples'; and Dire Dawa.

Table 2 Clinical Characteristics of Respondents in Tikur Anbessa Specialized Hospital, Addis Ababa, 2020

Variables	Category	Frequency (n = 158)	Percent (%)
Cancer site	Colon	73	46.2
	Rectum	85	53.8
Type of treatment	Chemotherapy only	78	49.4
	Surgery and radiotherapy only	16	10.1
	Chemotherapy and surgery only	34	21.5
	Chemotherapy and radiotherapy only	17	10.8
	CSR	12	7.6
	Radiotherapy only	1	0.6
Treatment intent	Curative	38	24.1
	Palliative	120	75.9
Cancer stage	Stage I	7	4.4
	Stage II	24	15.2
	Stage III	13	8.2
	Stage IV	114	72.2

Abbreviation: CSR, chemotherapy, surgery and radiotherapy.

Table 3 Cronbach's Alpha Values of EORTC-QLQ-CR29 Scales in Tikur Anbessa Specialized 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

EORTC-QLQ-CR29 among three clinically-distinct groups were made. These three groups were treatment intent, presence of stoma and physical function. This study hypothesised that patients with a stoma had a higher symptom score for Embarrassment and a lower functional score for the 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 scores for functional scales and items.

The Mann-Whitney test revealed that there was no significant difference between the curative and the palliative treatment groups in any of the scores of the colorectal tool scales or items. In patients with and without a stoma, the presence of a stoma led to a deterioration in quality of life by increasing Urinary Frequency, Flatulence, Embarrassment and Anxiety.

Table 4 Construct Validity for EORTC-QLQ-CR29 Scales in Tikur Anbessa Specialized Hospital, Addis Ababa, 2020

Scale	Item Numbers	Item-Own Scale Correlation	Item-Own Scale Correlation After Correction Overlap	Item-Other Scale Correlation	P-value
Urinary Frequency	31, 32	0.94–0.96	0.81	−0.33–0.34	<0.001
Blood and Mucus in Stool	38, 39	0.74–0.79	0.24	−0.31–0.35	<0.001
Stool Frequency	52, 53	0.92–0.93	0.73	−0.33–0.35	<0.001
Body Image	45–47	0.75–0.81	0.51–0.55	-(0.4–0.19)	<0.001

Table 5 The Correlation Between the Core EORTC QLQ and CR 29 Scales in Tikur Anbessa Specialized Hospital, Addis Ababa, 2020

	PF	RF	PA	FA	NV	CF	EF	SF	QoL
Urinary Frequency	−0.04	−0.01	−0.01	0.01	0.01	0.11	−0.23[b]	−0.02[a]	0.12
Urinary Incontinence	−0.24[b]	−0.24[b]	0.17[a]	0.17[a]	0.14	−0.23[b]	−0.21[b]	−0.39[b]	0.09
Dysuria	−0.275[b]	−0.34[b]	0.30[b]	0.24[b]	0.43[b]	−0.210[b]	−0.33[b]	−0.32[b]	−0.13
Abdominal Pain	−0.14	−0.10	0.38[b]	0.36[b]	0.24[b]	−0.14	−0.08	−0.04	0.07
Buttock Pain	−0.13	−0.19[a]	0.09	0.02	0.24[b]	0.10	−0.14	−0.19[a]	−0.19[a]
Bloating	−0.27[b]	−0.23[b]	0.21[b]	0.25[b]	0.17[a]	−0.19[a]	−0.31[b]	−0.15	0.09
Blood and Mucus in Stool	−0.17[a]	−0.10	0.24[b]	0.35[b]	0.18[a]	−0.35[b]	−0.17[a]	−0.13	0.26[b]
Dry Mouth	−0.30[b]	−0.12	0.20[a]	0.33[b]	0.02	−0.25[b]	−0.21[b]	−0.17[a]	0.25[b]
Hair Loss	−0.35[b]	−0.27[b]	0.36[b]	0.30[b]	0.38[b]	−0.36[b]	−0.09	−0.20[a]	0.04
Taste	−0.31[b]	−0.32[b]	0.40[b]	0.44[b]	0.32[b]	−0.31[b]	−0.06	−0.19[a]	−0.03
Anxiety	0.29[b]	0.26[b]	−0.02	−0.05	−0.01	−0.07	0.33[b]	0.23[b]	0.10
Weight	0.31[b]	0.24[b]	−0.11	−0.15	−0.21[b]	0.21[b]	0.32[b]	0.333[b]	−0.05
Body Image	0.45[b]	0.26[b]	−0.30[b]	−0.29[b]	−0.22[b]	0.25[b]	0.58[b]	0.30[b]	0.00
Flatulence	−0.41[b]	−0.31[b]	0.37[b]	0.11	0.35[b]	−0.45[b]	−0.12	−0.28[b]	0.15
Faecal Incontinence	−0.32[b]	−0.43[b]	0.29[b]	0.17[a]	0.30[b]	−0.39[b]	−0.34[b]	−0.34[b]	0.04
Sore Skin	−0.20[a]	−0.37[b]	0.28[b]	0.04	0.37[b]	−0.11	−0.33[b]	−0.239[b]	0.08
Stool Frequency	−0.23[b]	−0.31[b]	0.17[a]	0.11	0.18[a]	0.06	−0.38[b]	−0.14	−0.07
Embarrassment	−0.12	−0.16[a]	0.03	0.09	0.08	0.06	−0.31[b]	−0.11	0.10
Stoma Care Problem	−0.15	−0.12	0.03	−0.08	−0.03	0.07	−0.26[b]	−0.14	−0.07
Sexual Interest Men	−0.14	−0.11	0.05	0.11	0.03	0.04	0.02	−0.16[a]	−0.12
Impotence	0.03	0.15	−0.09	−0.08	−0.17[a]	−0.02	−0.04	0.02	0.15
Sexual Interest Women	−0.09	−0.08	0.06	−0.09	−0.14	−0.04	−0.06	0.00	0.17[a]
Dyspareunia	0.08	0.11	−0.07	0.07	0.11	0.01	0.05	−0.06	−0.12

Notes: [b]Correlation is significant at the 0.05 level, [a]Correlation is significant at the 0.01 level.
Abbreviations: PF, physical function; RF, role function; PA, pain; FA, fatigue; NV, nausea and vomiting; CF, cognitive function; EF, emotional function; SF, social function; QoL, quality of life.

Patients with better physical function scored higher for functional items and scales and scored lower for symptom items and scales. This suggested the known-groups validity of the tool is fulfilled. (Details are presented in Table 6.)

Discussion

The purpose of this study was to examine the reliability and construct validity of the Amharic version of the EORTC-QLQ-CR29 among Ethiopian colorectal cancer patients. In our study, the tool was found to be reliable. Its internal consistency values ranged from 0.47 to 0.91. All scales had Cronbach's alpha values of above 0.7, except for the Blood and Mucus in Stool scale. This finding concurs with the Dutch and original studies.[24–28] However, this finding differed from Korean and Taiwanese studies,[17,18] which found Cronbach-alpha values of greater than 0.7 for all scales.

Table 6 Known-Groups Comparison: Scales and Items in the EORTC-QLQ-CR29 for Clinically-Distinct Groups in Tikur Anbessa Specialized Hospital, Addis Ababa, 2020

CR-29	Treatment Mean Rank Value			Presence of Stoma			Physical Function		
	Curative	Palliative	P value	Yes	No	P value	Worse	Better	p-value
	n = 38	n = 120		n = 60	N = 98		n = 79	n = 79	
BI	76.03	80.60	0.84	79.01	79.80	0.92	66.99	92.01	<0.001
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	<0.001
HRL	87.16	77.08	0.60	66.35	87.55	<0.001	93.04	65.96	<0.001
TAT	75.39	80.80	0.99	68.37	86.32	0.01	90.32	68.68	<0.001
FLU	76.59	80.42	0.99	89.68	73.27	0.02	95.54	63.46	<0.001
FEI	74.55	81.07	1.00	88.01	74.29	0.05	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	<0.001	82.70	76.30	0.34
SCR	34.19	29.48	0.47	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

Abbreviations: BI, body image; AN, anxiety; WET, weight; SXM, sexual interest (men); SXF, sexual interest (women); UFR, urinary frequency; BM, blood and mucus in stool; STF, stool frequency; URI, urinary incontinence; DYS, dysuria; ABP, abdominal pain; BTP, buttock pain; BLO, bloating; DRM, dry mouth; HRL, hair loss; TAT, taste; FLU, flatulence; FEI, faecal incontinence; SOS, sore skin; EMB, embarrassment; SCR, stoma care problem; IMP, impotence; DYP, dyspareunia; NA, not applicable.

All-items correlations within their scales were greater than 0.4, except for the Blood and Mucus in Stool scale. This is similar to the results seen in a Spanish study.[16] However, this is inconsistent with the previous findings where it was shown that the Blood and Mucus in Stool scale had convergent and divergent validity.[17–19,24,28] The different findings reveal that limited variability in item score has an effect on correlation.[29] Thus, lower variability in our study might explain the difference. In fact, the items that comprise the Blood and Mucus in Stool scale may not correlate with each other.

Known-group comparison was performed to check whether the tool was able to detect differences between distinct groups. Our findings are consistent with studies conducted in Spain, China and the Netherlands,[16,19,24,28] where the tool was found to differentiate between the groups. However, the Body Image and Sore Skin items did not discriminate between patients with and without stoma. This is inconsistent with previous findings where a difference was seen according to the presence of a - stoma.[16,19,24,28] This difference might be due to the fact that, in our study, there was an age difference between stoma and non-stoma patients. However, the previous studies did not report the age of stoma and non-stoma patients. In the current study, patients in the stoma groups were older than those in the non-stoma groups. Based on a study conducted in Australia, elderly patients have a greater appreciation for their function and body image.[30] Similarly, the scales and items did not differentiate curative and palliative patients. This could be explained by the fact that, in our study, the sample size is smaller in the curative group.

The correlation between the core EORTC-QLQ and CR29 ranged from "weak" to "moderate". The highest correlation was observed between the Emotional and Body Image scales. This agrees with studies conducted in Korea and Spain.[16,18] This result suggests that the tools are designed to cover different dimensions of health-related quality of life. Therefore, the core questionnaire should be used along the specific module.

In general, the original tool was made in English. English is not widely spoken in Ethiopia. Therefore, the tool may not be understood in the same way in Ethiopia. There are also cultural differences between Ethiopia and where the original tool was first developed. On top of all these, there is also a lack of studies on the validity of the tool in Africa. Thus, this study can fill the gaps observed in Africa.

Strengths and Limitation of the Study

While the translation of the tool was done, every step of the EORTC translation process was followed, under the supervision of the EORTC translation group. Nonetheless, this study had its own limitations. Even though patients were included irrespective of their place of residence, treatment and disease stage, most of them were in the final stages of cancer. This is because most cancer patients in Ethiopia come to hospital at the late stages of the disease.

Conclusion

The current study supported the reliability and validity of the Amharic version of the EORTC-QLQ-CR29 among Ethiopian colorectal cancer patients. We also recommend that researchers and clinicians use the core questionnaire alongside the disease-specific module while assessing health-related quality of life in colorectal cancer patients. Specific support for each patient should be focused on the individual domains and items which eventually contribute to lower quality of life.

Abbreviations

EORTC-QLQ, European Organization for Research and Treatment of Cancer Quality of Life questionnaire; EORTC-QLQ-CR29, European Organization for Research and Treatment of Cancer Quality of Life questionnaire for colorectal cancer patients; FACIT, Functional Assessment of Chronic Illness Therapy; GLOBOCAN, Global Organization Board of Cancer Association Network; PCA, Principal Component Analysis; QoL, Quality of life; SDS, The Symptom Distress Scale; WHO, World Health Organization.

Data Sharing Statement

The data are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

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. Permission to use the questionnaires was secured from the EORTC research group using an online form at https://qol.eortc.org/form. Informed written

consent was given by all participants. This study was conducted in accordance with the Declaration of Helsinki.

Disclosure

The authors declare that they have no conflicts of interest for this work.

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