Psychometric Properties of the EORTC QLQ-C30 in a Ugandan Context

Allen Naamala Mayanja (✉ namalallen@gmail.com)

Makerere University College of Health Sciences <https://orcid.org/0000-0001-9164-1820>

Lars E. Eriksson

Karolinska Institutet / City, University of London

Jackson Orem

Uganda Cancer Institute

Gorrette Kayondo Nalwadda

Makerere University

Zarina Nahar Kabir

Karolinska Institutet

Lena Wettergren

Uppsala University / Karolinska institutet

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Abstract

Background

Self-reported measures play a crucial role in research, clinical practice and health assessment. Instruments used to assess self-reported health-related quality of life (HRQoL) need validation to ensure that they measure what they are intended to, detect true changes over time and differentiate between subjects. A generic instrument measuring HRQoL adapted for use among people living with cancer in Uganda is lacking; therefore, this study aimed to evaluate the psychometric properties of the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 when used in a Ugandan context.

Methods

Adult patients with various types of cancer (N=385) cared for at the Uganda Cancer Institute answered the Luganda or English version of the EORTC QLQ-C30. The two language versions were evaluated with regard to data quality (floor and ceiling effects and missing responses), reliability (internal consistency) and validity (construct, known-group and criterion). Construct validity was examined through confirmatory factor analysis (CFA). Mean scores were compared between groups differing in disease stage to assess known-group validity. Criterion validity was examined according to associations between two QLQ-C30 subscales (Global quality of life and Physical function) and the Karnofsky Performance Scale (KPS).

Results

Floor and ceiling effects were observed for several scales in the Luganda and English versions. All EORTC scales with the exception of Cognitive function (Luganda $\alpha=0.66$, English $\alpha=0.50$) had acceptable Cronbach's alpha values (0.79–0.96). The CFA yielded good fit indices for both versions (RMSEA=0.076–0.081, SRMR=0.048 and CFI=0.928–0.932). Known-group validity was demonstrated with statistically significant better HRQoL reported by patients with disease stages I–II compared to those in stages III–IV. The Global quality of life and the Physical function scales correlated positively to KPS ($r=0.65$ and $r=0.75$), indicating criterion validity.

Conclusion

The Luganda and English versions of the EORTC QLQ-C30 appear to be valid and reliable measures and can be recommended for use in clinical research to assess HRQoL in adult Ugandans with cancer. However, the cognitive scale did not reach acceptable internal consistency and needs further evaluation.

Background

The burden of cancer is expected to increase worldwide by more than 85% by 2030 (1, 2). Being diagnosed with cancer and undergoing its treatment may have a negative impact on patients' health-related quality of life (HRQoL) and cause multiple concerns (3). Where HRQoL is known, it helps to clarify

what actions, interventions or resource allocations that are necessary to help patients overcome their difficulties (4).

The few studies that have investigated HRQoL in persons suffering from cancer in East Africa present an overall negative picture. One such study conducted in Uganda assessed women with ovarian cancer using the abbreviated version of the World Health Organisation Quality of Life instrument and they found that patients scored poorly across domains (5). An interview study conducted in the same country explored adult cancer patients' experiences of chemotherapy (6). The results revealed that receiving chemotherapy was experienced challenging and associated with side-effects that negatively influenced patients' bodies and moods.

A few other studies focusing on HRQoL have been conducted in Tanzania and Kenya. Masika and co-workers assessed HRQoL using a standardised measure and conducted focus group interviews with hospitalised patients (7). Their results demonstrated low overall HRQoL, specifically with regard to financial situation and pain. These findings were supported by results from a cross-sectional study conducted in Kenya of approximately 150 women undergoing palliative treatment for cervical cancer (8).

HRQoL is typically measured with standardised instruments. One such instrument developed for use in clinical trials by the European Organisation for Research and Treatment of Cancer (EORTC) is the EORTC QLQ-C30. It was originally developed in English to investigate HRQoL in patients participating in clinical trials (9). The instrument has been widely used and translated into more than 100 languages worldwide; however, among countries in Sub-Saharan Africa, it has only been translated into Kiswahili, Xhosa, Afrikaans and Amharic (10). In Uganda no valid and reliable instrument for assessment of generic HRQoL in adults with cancer exist. Therefore, in this study, we set out to evaluate the psychometric properties of the Luganda and English versions of the EORTC QLQ-C30 in a Ugandan context.

Methods

The study employed a cross-sectional design.

The EORTC QLQ-C30

The EORTC QLQ-C30 version 3 consists of 30 items divided into nine multi-item subscales and six single items representing various aspects of HRQoL (9). The multi-item scales include five functional scales (physical, role, emotional, cognitive and social), three symptom scales (fatigue, nausea/vomiting and pain) and a global health and quality-of-life scale (Global QoL). Additionally, six single items measure impact on symptoms of dyspnoea, insomnia, loss of appetite, constipation, diarrhoea and the perceived financial impact of the disease (9).

All items have four response alternatives that range from 1 to 4 ('not at all', 'a little', 'quite a bit' and 'very much'), with the exception of the two items comprising the Global QoL scale, which have a score ranging from 1 (very poor) to 7 (excellent). According to the EORTC QLQ-C30 Scoring Manual, raw scores in QLQ-

C30 are linearly transformed to 0–100 point scales (11). For Global health status and the five functioning status, a score of 100 corresponds to a high HRQoL, whereas for financial difficulties and the eight symptoms, a score of 100 implies maximum difficulty or symptom burden (11, 12).

Translation of the EORTC QLQ-C30 to Luganda language

For the purposes of this study, the version 3 of the instrument was translated into the Luganda language and linguistically validated by our research group in accordance with the procedure developed by EORTC (13). First, two independent translators, native Luganda speakers with proficiency in English, translated the original English version into Luganda. The two translations were compared by the research coordinator, and any identified discrepancies were discussed with the translators until agreement was reached on a provisional forward translation. The preliminary Luganda version was then translated back into English by two other independent translators who were native Luganda speakers but also fluent in English. The translated English version was compared with the original English version of the questionnaire to ensure that there were no differences in the meaning of the questions.

The preliminary Luganda version was subsequently pilot tested on 35 adult cancer patients, native Luganda speakers treated and cared for at the Uganda Cancer Institute (UCI) (14). Trained nurses read out each item to the patients who were asked to answer and identify any questions that were difficult to understand, confusing, upsetting or perceived as offensive (15). The translated report was reviewed by the EORTC translation coordinator before the Luganda version of the EORTC QLQ-C30 was authorised by the EORTC Quality of Life Group.

Study setting

The present study was conducted at UCI, which is the only public hospital providing specialised cancer services in Uganda. The services include screening, radiotherapy, chemotherapy, counselling, training programmes, rehabilitation and palliative care. Additionally, research and consultation services are offered to promote better cancer control and care in the country. The institute offers care for in- and outpatients and has a bed capacity of more than 100 inpatients organised into five clinical units: two units for children and three for adults (solid tumour centre, lymphoma treatment centre and an outpatient department). Annually, UCI receives over 60,000 new cancer cases of both men and women, of which cervical cancer and Kaposi sarcoma account for 19.7% and 13% of cases, respectively (16).

Sample

Adult (≥ 18 years) patients with cancer, treated and cared for at UCI, speaking Luganda or English languages, with physical and mental ability (this was judged by the respective unit in-charges), were identified for possible participation in the study. A total of 482 patients were approached and screened for eligibility. Of the approached patients, 75 were excluded due to the following: poor health ($n = 23$), ongoing staging investigations ($n = 15$), cognitive difficulties ($n = 5$) or language barrier ($n = 32$). Eligible patients ($n = 407$) were asked to answer the Luganda or English versions of EORTC QLQ-C30 during a 4-week period (June–July 2019). Data was collected by seven registered nurses who had been trained for

the data collection procedure. Twenty-two patients refused to participate, whereas 385 consented to participate and subsequently answered the EORTC QLQ-C30 in Luganda (n = 217) or English (n = 168) by interview, resulting in a response rate of 95%.

Additional measures

The Karnofsky Performance Scale

All participants were assessed with the Karnofsky Performance Scale (KPS) index in addition to EORTC QLQ-C30. The KPS is an 11-point rating scale ranging from 100 (normal, no complaints) to 0 (dead) (17). Thus, lower values indicate worse functioning. It is used to describe patients' functional status and their medical care needs and is typically used as a selection criteria for clinical trials (18, 19). Furthermore, the instrument may be used to compare functional abilities across populations as well as evaluating the effectiveness of different therapies (17, 20). The nurses who collected data used their clinical experience together with medical records to assess, judge and rate patients' functional performance levels. The performance status was introduced to describe the patient's ability to carry out her or his normal activity and work or her or his need for a certain level of custodial care or dependence on constant medical care (18).

Following the literature, in the current study, patients were categorised into three groups (18): Patients rated with KPS of 100–80% were categorised as able to carry on with normal activity and work with no special care needs, patients rated at 70–50% were categorised as needing a varying degree of assistance, unable to work but could take care of most personal needs from home while those rated at KPS 40–0% were categorised as unable to care for themselves and required urgent care.

Socio-demographic and clinical data

Demographic data were collected using study-specific items to assess sex, age, marital status, number of children and household members, level of education and employment status. Clinical information was collected through medical records and included cancer diagnosis and stage, date of diagnosis and type of received cancer treatment.

Data analyses

Statistical analyses were performed in Stata version 14 (21). Data were analysed by language version, with the exception of known-group validity and criterion validity, which were calculated on the whole sample (Luganda and English versions). Analysis of data quality included distribution of scale scores (item means and standard deviations, floor and ceiling effects and missing item responses). The raw scores were used for psychometric evaluation, with the exception of floor and ceiling effects, which on the transformed scores (11). Floor and ceiling effects were calculated and considered acceptable if they did not exceed 15% (22). Cronbach's alpha was used to assess internal consistency. For this measure, values ≥ 0.7 are considered ideal; however, some researchers consider values < 0.70 but close to 0.60 as satisfactory (23).

Construct validity was ascertained using confirmatory factor analysis (CFA), which was performed to determine the adequacy of the original EORTC QLQ-C30 on our data by language version. Standardised coefficients of ≥ 0.4 were considered acceptable (24). Model fit was estimated by two absolute indices of overall model fit: root mean square error of approximation (RMSEA) and standardised root mean residual (SRMR). Additionally, one relative index of model fit was used: comparative fit index (CFI). The acceptable thresholds for these indices were defined as RMSEA = 0.05–0.08, SRMR < 0.08 and CFI > 0.90 according to Kline's guidelines (25). The degrees of freedom were reported, but not considered as an indicator of model fit owing to their restrictiveness of being sensitive to sample size (26).

Known-group validity was evaluated by examining the instrument's capacity to discriminate between patients differing in disease stage (stages I–II vs. stages III–IV). Independent t-tests were calculated to investigate potential differences in the mean scores of the EORTC QLQ-C30 scales between the two groups. Effect sizes (ES) were calculated to indicate the clinical significance of possible differences in means, whereby ES = 0.2, 0.5–0.8 and > 0.8 were considered small, moderate and large difference, respectively (27).

Criterion validity was determined by calculating correlation coefficients between two of the EORTC QLQ-C30 subscales (Physical function and Global QoL) and the KPS (28). It was hypothesised that the selected QLQ-C30 subscales would correlate positively to KPS with coefficients of large magnitude (28).

Procedure

Data was collected by seven trained research assistants (nurses), who approached patients in the clinical units. Patients were identified through patient lists generated by the study coordinator at the wards and outpatient department. The lists were used to evenly distribute participants among data collectors with the help of unit in-charges as well as planned appointments.

Potential participants were given written and oral information in Luganda or English about the aim and procedures of the study. It was stressed that participation was voluntary and that non-participation would not affect care and treatment in any way. Informed consent was asked for, and those patients who could not provide consent in writing were asked to do so through thumb print. Due to the large number of patients seen at UCI who could not read nor write, the questions were read to all patients. Additional demographic and clinical data were collected from patients' clinical records at UCI.

Results

The sample included 385 adult cancer patients (66% women and 34% men aged 18–84 years) who answered the Luganda (n = 217) or English (n = 168) versions of the EORTC QLQ-C30. The sociodemographic characteristics of the sample are presented in Table 1. The clinical characteristics of the patients are presented in Table 2 and reveal that most participants (65%) were in-patients with cancers in stages III and IV. Furthermore, approximately 60% had received chemotherapy, and one quarter had received radiotherapy.

Table 1

Socio-demographic characteristics by language version, Luganda (n = 217) and English (n = 168)

	Total n (%)	Luganda n (%)	English n (%)	χ^2 ^a	Df	P-value
Sample size	385 (100)	217 (100)	168 (100)			
Sex				1.10	1	0.294
Female	254 (66)	148 (68.2)	106 (63.1)			
Male	131 (34)	69 (31.8)	62 (36.9)			
Marital status				2.96	1	0.085
Married/cohabiting	217 (56.4)	114 (52.5)	103 (61.3)			
Widowed/single/ Divorced	168 (43.6)	103 (47.5)	65 (38.7)			
Home region				65.58	4	< 0.001
Northern	56 (14.5)	7 (3.2)	49 (29.2)			
Eastern	63 (16.4)	28 (12.9)	35 (20.8)			
Western	90 (23.4)	56 (25.8)	34 (20.2)			
Central	171 (44.4)	123 (56.7)	48 (28.6)			
Non-Ugandan	5 (1.3)	3 (1.4)	2 (1.2)			
Education level				46.83	3	< 0.001
Tertiary	65 (16.9)	15 (6.9)	50 (29.8)			
Secondary	123 (31.9)	63 (29)	60 (35.7)			
Primary	143 (37.1)	100 (46.1)	43 (25.6)			
None	54 (14)	39 (18)	15 (8.9)			
Occupation				17.58	3	0.003
Employed/farmer/business	323 (83.9)	181 (83.4)	142 (84.5)			
Student	14 (3.6)	5 (2.3)	9 (5.4)			
Housewife	8 (2.1)	4 (1.8)	4 (2.4)			
None	40 (10.4)	27 (12.4)	13 (7.7)			
^a Differences in proportions tested with χ^2 statistics						

Patients' socio-demographic characteristics differed by language version with regard to home region and education level. A majority of English speakers had more than primary education, and their home region was more or less evenly distributed in the different parts of Uganda, whereas approximately half of the Luganda speakers had primary education and came from the central part of the country. There were no statistical relations noted among clinical variables and the language version used.

Table 2
Clinical characteristics by language version, Luganda (N= (217) and English (N = 168)

	Total n (%)	Luganda n (%)	English n (%)	χ^2^b	Df	P-value
Sample size	385 (100)	217 (100)	168 (100)			
Clinical setting				0.39	1	0.533
In Patient	257 (66.8)	142 (65.4)	115 (68.5)			
Out Patient	128 (33.2)	75 (34.6)	53 (31.5)			
Diagnoses				11.61	9	0.236
Cervical	92 (24%)	60 (28%)	32 (19%)			
Breast	68 (18%)	32 (15%)	36 (21%)			
KS	43 (11%)	28 (13%)	15 (9%)			
Leukemias	26 (7%)	14 (6%)	12 (7%)			
Prostate	22 (6%)	12 (6%)	10 (6%)			
Oesophageal	20 (5%)	8 (4%)	12 (7%)			
Lymphomas	18 (5%)	7 (3%)	11 (7%)			
Lung	8 (2%)	5 (2%)	3 (2%)			
Ovary	8 (2%)	4 (2%)	4 (2%)			
Others	80 (21%)	47 (22%)	33 (20%)			
Cancer Stage				1.39	1	0.499
Early (I & II)	99 (25.7)	51 (23.5)	48 (28.6)			
Late (III & IV)	208 (54)	122 (56.2)	86 (51.2)			
Not reported ^a	78 (20.3)	44 (20.3)	34 (20.3)			
Type of treatment				0.02	1	0.813
Chemotherapy	235 (61)	130 (59.9)	105 (62.5)			
Radiotherapy	94 (24.4)	51 (23.5)	43 (25.6)			
Surgery	38 (9.9)	21 (9.7)	17 (10.1)			
Palliative	15 (3.9)	12 (5.5)	3 (1.8)			
No treatment yet	3 (< 1)	3 (< 1)	-			
Grouped KPS				0.41	2	0.813

	Total n (%)	Luganda n (%)	English n (%)	χ^2 ^b	Df	P-value
10 to 40	58 (15.1)	34 (15.7)	24 (14.3)			
50 to 70	162(42.1)	93 (42.9)	69 (41.1)			
80 to 100	165 (42.9)	90(41.5)	75 (44.6)			
^a Missing data						
^b Differences in proportions tested with χ^2 statistics.						
DF, Degrees of freedom						

Data quality

There were no missing item responses. Item means within subscales were roughly equivalent, and the standard deviations were close to 1 with the exception of the Global QoL scale. All response alternatives were used for all items. Floor effects in the Luganda version ranged between 5.5% and 53.0%, and ceiling effects ranged between 3.7% and 27.2% (Table 3). The corresponding floor effects for the English version ranged from 3.6–58.3%, and ceiling effects from 3.6–29.8%.

Table 3
Descriptive statistics for the subscales of EORTC QLQ-C30 by language version, Luganda (N = 217) and English (N = 168)

Subscales (no of items)	Mean ^a (SD)	Range of item means (SD)	Floor/ceiling effect ^b , %	Cronbach's α
PF (5)				
Luganda	2.47 (0.91)	1.74–3.10 (1.10–1.19)	8.8/9.2	0.86
English	2.31 (0.95)	1.61–2.90 (1.01–1.24)	7.7/14.9	0.88
RF (2)				
Luganda	3.00 (1.02)	2.89–3.10 (1.05–1.09)	35.5/11.5	0.91
English	2.77 (1.10)	2.77–2.77 (1.13–1.17)	28/18.5	0.90
EF (4)				
Luganda	2.29 (0.96)	2.16–2.38 (1.08–1.12)	9.7/13.8	0.89
English	2.26 (0.98)	2.15–2.52 (1.08–1.15)	8.9/21.4	0.91
CF (2)				
Luganda	2.17 (1.00)	2.12–2.21 (1.13–1.18)	11.1 /26.3	0.66
English	2.03 (0.91)	1.90–2.15 (1.08–1.15)	5.4/29.8	0.50
SF (2)				
Luganda	3.03 (1.03)	3.02–3.03(1.10–1.16)	41.0/9.7	0.79
English	3.08 (0.98)	3.01–3.15(1.01–1.12)	42.9/6.5	0.81
FA (3)				
Luganda	2.66 (0.96)	2.52–2.84 (1.04–1.08)	7.8/18.0	0.89
English	2.50 (0.98)	2.42–2.55(1.09–1.16)	14.3/9.5	0.85
NV (2)				
Luganda	1.82 (1.07)	1.72–1.93(1.07–1.16)	53.0/11.1	0.92
English	1.61 (0.92)	1.44–1.79 (0.88–1.08)	58.3/5.4	0.85

Subscales (no of items)	Mean ^a (SD)	Range of item means (SD)	Floor/ceiling effect ^b , %	Cronbach's α
PA (2)				
Luganda	2.83 (0.99)	2.80–2.86(1.05–1.10)	9.2/27.2	0.83
English	2.70 (1.08)	2.70–2.70(1.10–1.18)	16.7/24.4	0.89
Global QOL (2)				
Luganda	4.02 (1.51)	4.02–4.02 (1.54–1.56)	5.5 / 3.7	0.94
English	3.93 (1.53)	3.89–3.98 (1.55–1.57)	3.6/ 3.6	0.96
^a Means and standard deviations have been calculated using raw scores why higher scores indicate better HRQoL and more symptoms. ^b Floor and ceiling effects have been calculated using transformed scores PF; Physical function, RF; Role function, EF; Emotional function, CF; Cognitive function, SF; Social function, FA; Fatigue, NV; Nausea and vomiting, PA; Pain, Global QoL; Global quality-of-life.				

Reliability

Cronbach's α ranged from 0.66 to 0.94 for the Luganda version and from 0.50 to 0.96 for the English version (Table 3). The Cognitive function scale had the lowest α (0.66, Luganda version; 0.50, English version).

Construct validity

The CFA was performed separately on responses from the two versions: Luganda (N = 217) and English (N = 168). Both versions provided statistically significant models: namely, Luganda $\chi^2 = 458.161$ ($p < 0.001$) and English version $\chi^2 = 490.068$ ($p < 0.001$) with standard factor loading estimates ranging from 0.50 to 0.97 for the Luganda version and from 0.60 to 0.96 for the English version. The fit statistics of the CFA conducted on the Luganda version provided an RMSEA of 0.081 (90% CI: 0.070–0.091), an SRMR of 0.048 and a CFI of 0.928; the corresponding values for the English version were RMSEA = 0.076 (90% CI: 0.068–0.085), SRMR = 0.048 and CFI = 0.932.

Known-group validity

Mean values for early (I–II) and late (III–IV) stages of the disease (both language versions) are presented in Table 4. In 6/9 subscales, statistically significant differences were detected between patients with late stage disease who rated worse functioning and more symptoms compared to those in early stages. ES

ranged between small and medium, with Physical function displaying the highest ES (0.72). Some participants (n = 78) were still undergoing staging investigations and were not included in the analysis.

Table 4

Significant differences in self-reported HRQoL by disease stage, stage I-II (n = 99) compared to stage III-IV (n = 208)

QLQ-C30 subscales	Stage I-II	Stage III-IV	P-value ^b	Effect size
	Mean ^a (SD)	Mean ^a (SD)		
Global Quality of life	56.40 (25.31)	45.51 (25.23)	< 0.001	0.43
Physical function	64.18 (26.54)	45.06 (31.54)	< 0.001	0.72
Role function	46.30 (36.00)	30.45 (34.44)	< 0.001	0.46
Cognitive function	58.84 (31.63)	53.81(34.04)	NS	0.15
Emotional function	65.15(31.42)	58.65(33.97)	NS	0.21
Social function	23.57 (30.02)	30.29 (33.31)	NS	-0.22
Fatigue	47.36 (31.85)	59.62 (32.27)	≠0.01	-0.38
Nausea/vomiting	17.00 (29.35)	29.01 (35.78)	≠0.01	-0.40
Pain	53.20 (34.80)	65.06 (33.38)	≠0.01	-0.35
^a Mean scores range from 0 to 100 with higher scores in functional scales reflecting a better HRQoL and in symptom scales more symptoms. ^b Differences tested by student's unpaired <i>t</i> -test. NS, Non-significant				

Criterion-based validity

Positive correlations were revealed between the KPS and the subscales of Physical function (0.65) and Global QoL (0.75), both of large magnitude.

Discussion

This study reported on the psychometric evaluation of the English and Luganda versions of the EORTC QLQ-C30 when used in specialised cancer care in Uganda. Most importantly, the instrument demonstrated satisfactory validity in terms of construct and known-group validity as well as in criterion validity. However, even though the overall data quality was good with acceptable reliability (internal consistency) for all but one scale, considerable high floor and ceiling effects were detected for some scales, and this tendency merits some concern.

The participants of the study are patients cared for at UCI, with Luganda speakers mainly having an origin from Central Uganda and those answering the English version more evenly distributed over the country. The education level also differed between the language versions, with a higher proportion of patients with secondary and tertiary answering the English version, whereas a larger portion of the sample with primary education answered the Luganda version. This result reflects the population in Uganda and the patients seen at UCI (29).

Most Ugandans are peasant farmers who speak and conduct small scale businesses in local languages. No significant differences were found regarding gender, marital status and clinical characteristics with regard to language versions. This was expected considering the fact that cancer stage, type of treatment or status of KPS are independent of the language one speaks.

Data quality

All four response alternatives were used for all items (data not shown), suggesting that the response scale was sufficient. However, floor effects of approximately 30–50% were observed for the Role function, Social function and Nausea/vomiting scales, with a similar pattern observed for both language versions. Additionally, ceiling effects exceeding 25% were observed in the Cognitive function and Pain scales for both language versions. Furthermore, ceiling effect of the English version of the Emotional function scale was 21%. This distribution may indicate that a large proportion of patients in an advanced disease stage experienced diminished functioning regarding role and social functioning due to fatigue and pain.

The high floor effects for the Nausea/vomiting scale could indicate poor ability to differentiate between no symptoms and mild symptoms; however, based on clinical experience, it might probably be partially a consequence of low prevalence of these symptoms in this patient population (12). The high floor effects seen for the Nausea/vomiting scale was puzzling considering that approximately 60% of the patients were currently on chemotherapy and nausea and vomiting are well-known side effects of chemotherapy (30). The finding may be explained by inefficiencies regarding drug procurement, storage and distribution, which led to delays in drug delivery, expiry of drugs in stores, wrong deliveries and stock shortages of basic drugs despite the supply chain system by National Medical Stores (NMS). As a result, resources and lives were lost making treatment outcomes unsatisfactory and ultimately resulting in the poor performance of user institutions (31). In light of this background, the cancer drugs supplied at the time of the study might have experienced similar conditions with negative consequences on quality and quantity. Around October 2019, UCI took over the supply chain information management and service delivery for anti-cancer drugs. A study investigating chemotherapy side effects is ongoing to justify the current chemotherapy treatment outcomes (personal communication, Jackson Orem). Tentative results revealed the return of expected side effects; namely, nausea and vomiting, alopecia and diarrhoea.

Similar results were also demonstrated in a study to evaluate the HRQoL of adult Tanzanians with cancer using the EORTC QLQ-C30(7). Their results demonstrated high floor effects in the role and social functioning scales as well as in the nausea/vomiting subscale. Another study among Greek patients with

cancer of pharynx and larynx revealed large ceiling effects for all QLQ-C30 functional scales and floor effects for all symptom scales (32).

All scales but one had satisfactory reliability. The cognitive function scale displayed a Cronbach's alpha of 0.50 for the English version and of 0.66 for the Luganda version. A low alpha coefficient for the cognitive scale has been reported in other studies (7, 32). It has been argued that this may to some extent be due to the small number of items in the scale. One of the two items measuring cognitive function assesses the ability to concentrate on things ('like reading a newspaper or watching television'), activities that may appear inappropriate for Ugandans with cancer since newspapers and televisions are not available to patients at UCI. Furthermore, the literature has shown that Ugandans have low reading literacy (33). The other item in the scale asks about memory: 'Have you had difficulty remembering things'. Thus, it is understandable that the two items may not be highly correlated and subsequently results in a somewhat low alpha value. This was also revealed in a study conducted in Tanzania by Masika et al. (7).

The CFA supported the notion that the EORTC QLQ-C30 measures the intended nine multi-item scales of HRQoL. Standardised factor loadings and the goodness of fit for outputs of the Luganda and English versions demonstrated satisfactory results, suggesting strong construct validity (23).

The instrument demonstrated known-group validity as the EORTC QLQ-C30 was able to successfully discriminate between early and late stages of cancer among participants, such that patients with advanced disease demonstrated poorer HRQoL than those with early stages of the disease. Furthermore, ES revealed that the detected statistically significant differences were clinically relevant. Furthermore, the physical function and Global QoL scales were both associated with the KPS, with large correlation coefficients indicating criterion validity (23).

Strengths And Limitations

This is the first study of HRQoL using the generic EORTC QLQ-C30 to be performed in Uganda. The study had a large representative sample of adult men and women cared for at UCI, including both in- and outpatients. The study was conducted using the most commonly used languages in the country. Still, patients who could not speak and understand Luganda and or English were not able to participate in the study. Furthermore, despite high efforts to reach patients in the data collection period. Moreover, the cross-sectional design of the study prohibited any possibility to examine the instrument's test-retest reliability.

Conclusions

This first psychometric evaluation of the English and Luganda versions of the 30-item EORTC QLQ-C30 in a Ugandan context is promising. The instrument appears to be a valid and reliable measure, with the exception of the Cognitive function scale, in which we recommend that one item be rephrased to better

suit a Ugandan context. Furthermore, the floor effects noted for Role and Social functioning, reflecting low function, as well as the ceiling effect for the Pain subscale (high pain) may be an obstacle when conducting comparative studies. Apart from caution in interpreting cognitive function, the instrument is recommended for research among adult Ugandans with cancer.

Abbreviations

HRQoL: Health- Related Quality of Life, PACT: Program of Action for Cancer Therapy, RN: Registered Nurse QLQ-C30: Quality of Life Questionnaire (Version 3), UCI: Uganda Cancer Institute, WHO: World Health Organisation.

Declarations

Ethical approval and consent to participate

The study received ethical approval from the School of Health Sciences High Degree Research and Ethics Committee number (#SHSHDREC REF: NO 2016-045) as well as from the Uganda National Council for Science and Technology (UNCST: number SS4979). The Uganda Cancer Institute Research and Ethics Committee (UCIREC) provided administrative clearance number (SR: 120) to collect information from patients' medical records regarding type of treatment and cancer as well as certain socio-demographic information. Written informed consent and thumb stamping (for those who could not provide consent in writing) was collected from all participants before answering the survey.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are available from the principal investigators of the study on reasonable request.

Competing Interests

The authors declare that they have no competing interests. There are no financial and/or personal relationships between the authors and others that might bias the work.

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Authors' contribution

ANM, JO, GKN, LEE, LW and ZNK conceived and designed the study, conducted and supervised data collection as well as data analysis, and ANM, LEE, LW and ZNK wrote the manuscript. All authors approved the final version.

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