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PRELIMINARY PSYCHOMETRIC VALIDATION OF THE POLISH VERSION OF THE EORTC ELDERLY MODULE (QLQ-ELD14)

Abstract: Aim: The aim of our study was to report preliminary validation data on the EORTC translated, Polish version of the EORTC QLQ-ELD14 questionnaire to show that this tool is an acceptable and psychometrically robust measure to collect HRQoL data in Polish elderly patients with cancer.
Materials and Methods: Patients with histological confirmation of primary cancer were eligible for the study. All patients filled out the Polish version of the EORTC QLQ-ELD14 module in addition to EORTC QLQ-C30 and a demographic questionnaire. Standardized validity and reliability analyses were performed.
Results: Sixty-five patients (41 females — 63.1%) were enrolled into the study, with a mean age of 76.4 ± 5.7 years. Cronbach alpha coefficients, range 0.70–0.84, showed positive internal consistency. Satisfactory convergent and discriminant validity in multi-trait scaling analyses was seen. Strong correlations were observed between the EORTC QLQ-ELD14 (especially mobility and burden of illness), and the EORTC QLQ-C30 ($r = -0.30$–(-0.83); $p < 0.001$).
Conclusions: Basing on the preliminary data from this study, the Polish version of the EORTC QLQ-ELD14 module is a reliable and valid tool for measuring HRQoL in elderly cancer patients. However further research is needed to establish the full psychometric properties of the described module, especially in regards to test-retest and responsiveness over time..

Key words: ELD14, elderly, EORTC, psychometric, validation.

INTRODUCTION

In recent years, in addition to the traditional cancer outcome measures such as overall survival, disease-free survival, and time to disease progression, also health-related quality-of-life (HRQoL) received recognition [1]. This signifies an important change in thinking, as in many cancer patients successful medical results often coexist with unsatisfactory outcomes from the patient's own point of view [1, 2].

Over 50% of all new cancer diagnoses and over 60% of all cancer-related deaths occur in the elderly [3]. However, surprisingly despite the above mentioned fact, older people are still underrepresented in cancer clinical trials [4].

The most probable reason that might explain this state is that the vast majority of elderly patients, even though they qualify for active treatment, will not finish their treatment plan due to high mortality [5]. Further issues that might restrict access of elderly people to the full panel of treatment options are comorbidities, low social support, and frailty [6, 7].

HRQoL in the elderly is a complex construct encompassing more than just mental and physical health and functioning [8]. What is more, HRQoL in older patients is not linked to any specific medical condition [4]. A study by Wan *et al.* [9] has shown that it is cancer, and not age that impacts HRQoL in elderly patients. What is interesting, elderly cancer patients can have better HRQoL when compared to cancer-free patients [8, 10].

Older people often have a different HRQoL profile, when compared with younger patients, due to their specific age-related needs [11]. Even though a broad spectrum of tools, able to measure both general (eg. SF-36) [12] and cancer-specific HRQoL (eg. European Organization for Research and Treatment of Cancer — EORTC QLQ-C30) [13] exists, up until recently the literature lacked questionnaires targeted to assess cancer-related HRQoL in the elderly. In 2013 Wheelwright *et al.* [14] published on behalf of the EORTC Quality-of-Life Group a manuscript describing the creation of the EORTC QLQ-ELD14 — a supplementary module to the EORTC QLQ-C30 that allows to assess the HRQoL of elderly patients with cancer. To date no tool for assessing HRQoL in elderly cancer patients is available in Polish.

The aim of our study was to report preliminary validation data on the EORTC translated, Polish version of the EORTC QLQ-ELD14 questionnaire to show that this tool is an acceptable and psychometrically robust measure to collect HRQoL data in Polish elderly patients with cancer. Our group has previous experience in performing this kind of validation studies [15, 16].

MATERIALS AND METHODS

PATIENTS

The patients were recruited prospectively between January 2014 and June 2014 in one hospital and one private clinic in Krakow, Poland.

The research protocol was approved by the Jagiellonian University Ethics Committee (registry number KBET/187/B/2014). The study has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Patients were eligible if they were above 70 years old and had histological confirmation of primary cancer. Exclusion criteria included lack of consent to participate in the study, inability to understand or complete the questionnaires, and a history of any other cancer than the primary. The patients included were

classified into groups based on their current Karnofsky Performance Status (KPS) (>80 or ≤80), having none or one or more Charlson comorbidity, and being on or off treatment [17].

INTERVIEW PROCEDURE

The patients were approached during their visits at the outpatient clinics of the participating centers or during their stay at the clinic, and informed about the study. They were interviewed only after written informed consent was obtained. Each patient completed the Polish version of the EORTC QLQ-C30, the EORTC QLQ-ELD14 module and a questionnaire concerning demographic data together with the Charlson Comorbidity Index [18]. Patients were provided the measures before undergoing planned treatment. The questionnaires were administered by a medical doctor.

QUESTIONNAIRES

The EORTC QLQ-C30 is a 30-item questionnaire comprised of a global health status, five multi-item functional scales, three multi-item symptom scales and six symptom single items. It is translated into over 85 languages [19], and is one of the most frequently used HRQoL measures in clinical trials [20].

The EORTC QLQ-ELD14 is a 14-item cancer-specific module composed of five multi-item scales that assess mobility (3 questions), worries about others (2 questions), future worries (3 questions), maintaining purpose (2 questions), and burden of illness (2 questions). It also includes 2 single items regarding joint stiffness and family support. All questions of the EORTC QLQ-ELD14 have standardized scores ranging from 0 to 100, with higher scores indicating a greater degree of symptoms (worse HRQoL) (for questions number 31–34, 36–40, 43, 44), and a better HRQoL in case of questions number 35, 41, and 42 [14].

All of the EORTC QLQ-C30 and the EORTC QLQ-ELD14 multi-item scales and single items are scored on a 1- to 4-point Likert scale (‘not at all’, ‘a little’, ‘quite a bit’, ‘very much’), apart from items 29 and 30 of the EORTC QLQ-C30, which are scored on a 1- to 7-point scale. Detailed information on how to score the EORTC questionnaires can be found in the EORTC QLQ-C30 scoring manual and its addendum [21]. The questionnaire and the scoring manual were obtained from the EORTC Quality of Life Department, upon request of the main author of the study.

STATISTICAL ANALYSIS

Several pre-planned standard psychometric tests were conducted, these approaches can be seen in the EORTC Module Development Guidelines [22, 23].

Scoring of the two measures followed the standard EORTC scoring instructions. In short, scores for single items and multi-item functional and symptom scales were calculated by linear transformation of raw scores into a 0–100 score, with 100 representing best global health, functional status or worst symptoms — depending on the measuring property of each multi-item or single-item scale, as described by the EORTC Scoring Manual [21]. To analyze the data descriptive statistics (mean, standard deviation, percentage distribution) were used.

Convergent validity was assessed by correlating each item with its own scale. Discriminant validity was assessed by correlating each item with any other scale. Evidence of item convergent validity was defined as a correlation of 0.40 or greater between an item and its own scale (corrected for overlap). A scaling success for an item was seen when the correlation between an item and its own scale was significantly higher than its correlation with other scales [24]. Cronbach's alpha coefficient was calculated to assess the internal consistency of the Polish version of the EORTC QLQ-ELD14. Internal consistency estimates of a magnitude of >0.70 were considered acceptable for group comparisons [24].

Clinical validity was assessed using the Wilcoxon rank sum nonparametric test. This assesses if the questionnaire was able to discriminate between subgroups of patients differing in clinical status. Known-groups used in this study were based on Karnofsky Performance Status (KPS), Charlson Comorbidity Index, and being on or off treatment. Differences between groups were tested with the Mann–Whitney test. Spearman correlation was used to assess the correlations between the EORTC QLQ-C30 and the EORTC QLQ-ELD14 scales.

The significance level was set at $p < 0.05$. Statistical analysis was conducted using computer software Statistica 10.0 PL by StatSoft Poland (licensed to the Jagiellonian University Medical College).

The acceptability of the EORTC QLQ-ELD14 was assessed using the response rate, percentage of missing data, assistance and time needed to complete the questionnaire and details of items considered upsetting, confusing or difficult in the questionnaire.

RESULTS

PATIENT CHARACTERISTICS AND ACCEPTABILITY

During the 6-month recruitment period a total of 65 patients (41 females — 63.1%) were enrolled into the study, with a mean age of 76.4 ± 5.7 years. Patients' clinical and demographic data are presented in Table 1.

No patients refused to participate in the study. All 65 patients answered both the EORTC QLQ-C30 and the EORTC QLQ-ELD14. Overall 6.1% of item responses were missing.

In total 45 (69.2%) interviewees required assistance completing the questionnaires. The most commonly given justification were problems with eyesight and

Table 1

Patients' clinical and demographic data.

Variable	Overall n = 65
Age (mean±SD)	76.4 ± 5.7
Education (%)	
Elementary	17 (26.2%)
High School	34 (52.3%)
University	14 (21.5%)
Current working status (%)	
Employed (full-time)	2 (3.1%)
Employed (part-time)	11 (16.9%)
Retired/Pensioner	52 (80%)
Living (%)	
Alone	21 (32.3%)
With partner or family	36 (55.4%)
With others (e.g. nursing home)	8 (12.3%)
Marital status (%)	
Married	39 (60%)
Widowed	13 (20%)
Divorced	8 (12.3%)
Single	5 (7.7%)
Primary tumour (%)	
Breast	16 (24.6%)
Prostate	13 (20%)
Colorectal	12 (18.5%)
Head & Neck	12 (18.5%)
Lung	6 (9.2%)
Other	6 (9.2%)
Active treatment (%)	
Yes	29 (44.6%)
No	36 (55.4%)
Karnofsky Performance Status (%)	
>80	43 (66.2%)
≤80	22 (33.8%)
Charlson Comorbidity Index (%)	
No comorbidities	17 (26.2%)
One Charlson comorbidity	27 (41.5%)
More than one Charlson comorbidity	21 (32.3%)

SD — standard deviation.

reading. The total time for completion of the questionnaires and interview was approximately 25 minutes without assistance and 34 minutes with assistance. Seven patients (10.8%) found questions 37–39 (relating to their and their family health in the future, and uncertainty of what the future might bring) upsetting. No patients reported the questions to be confusing or difficult.

RELIABILITY AND VALIDITY

Reliability, convergent and discriminant validity of EORTC QLQ-ELD14 multi-item scales and single items are presented in Table 2. Taking into account the EORTC QLQ-ELD14 its own-scale correlations were considered good. All item correlations within their own scales exceeded the 0.40 criterion, and were correlated higher with their own scale than with the other scales. All presented Cronbach alpha values exceeded the 0.7 criterion.

Table 2

Reliability, convergent and discriminant validity of QLQ-ELD14 multi-item scales and single items.

EORTC QLQ-ELD14 multi-item scale and single items*	Convergent validity[1]	Discriminant validity[2]	Cronbach's alpha
Mobility (3)	0.57–0.63	0.04–0.46	0.81
Joint stiffness (1)	–	0.10–0.40	–
Family support (1)	–	0.03–0.41	–
Worries about others (2)	0.51	0.06–0.37	0.70
Future worries (3)	0.70–0.79	0.04–0.55	0.84
Maintaining purpose (2)	0.59	0.09–0.28	0.71
Burden of illness (2)	0.62	0.04–0.52	0.83

SD — standard deviation; * — the number in brackets signify the number of questions in the scale/ signify a single item; [1] — Item-own scale correlation, Spearman correlation coefficient, corrected for overlap [2] — Item-other scale correlation, absolute values displayed, Spearman correlation coefficient.

Clinical validity assessment by known-group comparison is presented in Table 3. There were significant differences between the groups in most of the EORTC QLQ-ELD14 scales and items.

Table 4 presents Spearman correlations values for correlations between the QLQ-C30 and the QLQ-ELD14 scales.

Table 3

EORTC QLQ-ELD14 known group comparison.

EORTC QLQ-ELD14	On (n = 29) vs. Off Treatment (n = 36)	One (n = 27) vs. more than one (n = 21) Charlsoncomorbidity	KPS >80 (n = 43) vs. KPS ≤80 (n = 22)
Mobility	42.7 vs. 29.0; p <0.0001	40.3 vs. 52.6; p <0.0001	16.6 vs. 51.3; p <0.0001
Joint stiffness	26.8 vs. 21.4; p <0.0001	37.1 vs. 45.4; p <0.0001	15.2 vs. 41.2; p <0.0001
Family support	79.3 vs. 70.9; p <0.0001	65.1 vs. 69.9; p<0.0001	68.4 vs. 82.0; p <0.0001
Worries about others	48.1 vs. 37.4; p <0.0001	37.7 vs. 37.0; p = 0.02	38.3 vs. 41.1; p <0.0001
Future worries	38.4 vs. 23.5; p <0.0001	29.5 vs. 37.2; p <0.0001	22.4 vs. 39.0; p <0.0001
Maintaining purpose	64.0 vs. 67.2; p <0.0001	68.6 vs. 61.4; p <0.0001	75.7 vs. 61.4; p <0.0001
Burden of illness	59.5 vs. 36.2; p <0.0001	36.5 vs. 50.1; p <0.0001	30.8 vs. 62.6; p <0.0001

Values presented as mean±SD; KPS — Karnofsky Performance Status; SD — standard deviation

Table 4

Spearman correlations values for correlations between the QLQ-C30 and the QLQ-ELD14 scales.

	Mobility	Joint stiffness	Family support	Worries about others	Future worries	Burden of illness	Maintaining purpose
Physical functioning	–0.83*	–0.50*	0.05	–0.12	–0.23	–0.45*	0.18
Social functioning	–0.43*	–0.29	0.11	–0.35	–0.40*	–0.50*	0.24
Emotional functioning	–0.30	–0.23	0.17	–0.29	–0.51*	–0.56*	0.31
Role functioning	–0.55*	–0.31	0.06	–0.20	–0.33	–0.48*	0.15
Global health status/quality of life	–0.57*	–0.39	0.19	–0.22	–0.43*	–0.51*	0.29

* — r ≥0.4

DISCUSSION

This study is a preliminary report aiming to establish the psychometric properties of the Polish version of the EORTC QLQ-ELD14 module in order to introduce it to clinical practice before the full validation data become available.

The EORTC QLQ-ELD14 module is different from other EORTC site-specific modules as it is applicable to patients with all kinds of malignancies, and has a stronger than normal focus on the psycho-social side of HRQoL problems [14].

As mentioned earlier, the elderly are still an underrepresented group in clinical trials [4], especially those encompassing HRQoL as an outcome. This partially stems from the fact, that in opposition to depression [25] or cognitive and physical disorders [26] instruments specifically tailored to assess HRQoL in the elderly have just recently been introduced [4, 14]. There is a need to complement classical oncologic outcomes with the use of measures of patients' perception on disease impact and treatment consequences.

None of the 65 patients approached declined taking part in the study. This is an important information signifying both that the EORTC QLQ-ELD14 is an acceptable measure, and that elderly cancer patients are ready and open to discuss their HRQoL problems with healthcare professionals. The low percentage of missing responses further backs this theory, at the same time showing that there are only a few issues that a minority of older people might be reluctant to discuss. A significant portion of study participants required assistance when filling in the questionnaires. The most common reason given by the patients was that due to lack of proper reading glasses they were unable to read the questionnaires by themselves. In the future this might be solved by using computerized adaptive testing (CAT) [27] which, among other things, allows to enlarge the text font to the size readible by the patient. Even though the total number of questions was lower than in similar questionnaire administered to younger adults [12, 16, 28], older patients required considerably more time to fill in the questionnaires. A minority of the participants found three questions of the EORTC QLQ-ELD14 upsetting — from one side this can be a purely incidental finding. However, healthcare professionals would do wise to take this into account, and approach elderly cancer patients with appropriate patience and empathy — traits that can be easily lost in the busy modern medical environment [29, 30].

Similar to the original EORTC Phase 4 study by Wheelwright *et al.* [14] the Polish version of the EORTC QLQ-ELD14 construct showed five multi-item scales and two single items characterized by appropriate reliability, convergent and discriminant validity. The results of known-group comparison demonstrated that the EORTC QLQ-ELD14 module is able to successfully discriminate between patient subgroups differing in clinical status.

The correlations found between the EORTC QLQ-C30 and the EORTC QLQ-ELD14 were not unexpected, and can be justified by the concept of the scales

themselves. These results point to the central role of mobility and burden of illness in the overall cancer-related HRQoL. The same was confirmed in the study by Wheelwright *et al.* [14]. What is interesting is the fact that psychometric analysis in the EORTC Phase 4 study [14] suggested to retain joint stiffness as a separate item from the mobility scale. This was further backed by qualitative reports from patients in the EORTC Phase 1 study [4], showing that elderly people see joint stiffness as a separate entity, when contrasted with problems with mobility.

The main limitations of this study stem from the fact that this is a preliminary report aiming to rapidly introduce the Polish version of the EORTC QLQ-ELD14 into clinical practice. The elements lacking in this manuscript i.e. responsiveness over time and test-retest will be assessed once the target sample size for the final analysis will be reached (n = 90–140; according to the proposal of Tabachnick and Fidell [31] stating that in order to obtain reliable estimates, the number of observations should be 5–10 times the number of questions in the questionnaire).

What appears to be the best application of the EORTC QLQ-ELD14 is to use it to supplement the EORTC QLQ-C30 (stacked together with an appropriate site-specific module) to fully evaluate generic issues affecting elderly people with cancer, that are not covered by the core module or its appropriate disease-specific add-on. Wheelwright *et al.* [14] suggest that the greatest use of the EORTC QLQ-ELD14 might be found when evaluating changes in cancer services across a range of tumor sites.

Clinicians should remember that even though new cancer treatment options arise almost every month, HRQoL should always accompany survival. Thus, the need for tools such as the one described in this study, which will hopefully help to include older Polish cancer patients in clinical trials having HRQoL as one of the endpoints.

Concluding, basing on the preliminary data from this study, the Polish version of the EORTC QLQ-ELD14 module is a reliable and valid tool for measuring HRQoL in elderly cancer patients. However further research is needed to establish the full psychometric properties of the described module, especially in regards to test-retest and responsiveness over time.

CONFLICT OF INTEREST STATEMENT

Conflict of interest — none declared.

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