Patient Preference and Adherence

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ORIGINAL RESEARCH

Validation of the European Organization for Research and Treatment of Cancer cervical cancer module for Chinese patients with cervical cancer

This article was published in the following Dove Press journal:
Patient Preference and Adherence
16 October 2013
Number of times this article has been viewed

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Purpose: The aim of our study was to assess, for the first time, the validity, reliability, and acceptability of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life questionnaire (QLQ) cervical cancer module (CX24) in Chinese cervical cancer patients.

Patients and methods: One hundred fifteen outpatients with cervical cancer in the First Affiliated Hospital of Xinxiang Medical University from May 2013 to July 2013 were included in this study. All participants self-administered the EORTC QLQ-CX24 and the core questionnaire (EORTC QLQ-C30), and the Karnofsky Performance Scale was performed to evaluate scores. Data were analyzed with Cronbach's α coefficient, Pearson correlation test, multitrait scaling analysis, and Mann–Whitney *U* test.

Results: Scale reliability was confirmed by Cronbach's α coefficients for internal consistency, which ranged from 0.71 to 0.82. Convergent and discriminant validity were confirmed by multitrait scaling analysis, which revealed three (3.4%) scaling errors for symptom experience scales and zero (0%) for body image as well as sexual/vaginal functioning scales. Higher missing value rate occurred in sexuality-related items. The clinical validity of the Chinese version of the EORTC QLQ-CX24 was demonstrated by the ability to discriminate among patients in different International Federation of Gynecology and Obstetrics stages.

Conclusion: The EORTC QLQ-CX24 was proved to be a reliable and valid instrument with which to measure the quality of life in cervical cancer patients in the People's Republic of China.

Keywords: cervical cancer, quality of life, EORTC QLQ-CX24, People's Republic of China

Introduction

Cervical cancer is the second most common malignancy worldwide and the third most frequent cause of cancer death among women. An estimated 140,000 new cases of cervical cancer occur annually in the People's Republic of China, which accounts for one-third of all the world's new cases of cervical cancer.[1] From 2003 to 2007, however, morbidity increased sharply from 7.14/100,000 to 11.74/100,000 due to the increased rates of infection with human papilloma virus, which has attracted extensive attention in the People's Republic of China.[2–6] Increasing the survival time and improving the quality of life (QOL) of patients with cervical cancer has become a priority task for gynecologic oncologists.

QOL assessment can be a useful tool for determining the outcomes of treatment for cervical cancer and aiding decisions regarding further therapy. However, a major drawback for the European Organisation for Research and Treatment of Cancer (EORTC)

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Quality of Life questionnaire (QLQ) core questionnaire (C30) to evaluate treatment options for cervical cancer has been the unavailability of EORTC QLQ-C30 to measure QOL issues specific to cervical cancer and its treatment as a valid and concise instrument. The EORTC QLQ cervical cancer module (CX24) aims to fill that gap. Although the EORTC QLQ-CX24 has been field-tested for psychometric properties in a multi-country study including Europe, South Korea, South Africa, and others, with satisfactory validity and reliability, patients from the People's Republic of China were not included.[7–9] The diversity between Chinese and Western culture results in different interpretations of QOL, so it is important to assess the validity, reliability, and acceptability of the EORTC QLQ-CX24 in the People's Republic of China.

Materials and methods

Participants

One hundred fifteen outpatients suffering from cervical cancer in the First Affiliated Hospital of Xinxiang Medical University, Weihui, People's Republic of China were contacted between May 2013 and July 2013. All patients were over 18 years old with the ability to understand and answer survey questions, and had been pathologically diagnosed with cervical cancer. Patients who were diagnosed with a cognitive disorder or psychonosema were excluded.

Instruments

EORTC QLQ-CX24

The EORTC QLQ-CX24 contains 24 items that can be summarized in three multi-item scales, namely, symptom experience (eleven items), body image (three items), and sexual/vaginal functioning (four items). The other dimensions of the questionnaire are single-item scales, covering lymphedema, peripheral neuropathy, menopausal symptoms, sexual worry, sexual activity, and sexual enjoyment.[8] The standard scoring algorithm recommended by the EORTC is used to linearly transform all scales and item scores to a 0–100 scale, with a higher score representing a better level of functioning (for items on sexual activity and sexual enjoyment) and a higher level of symptoms (for all other items and scales).[10]

EORTC QLQ-C30

The 30-item EORTC QLQ-C30 is a psychometrically robust, cross-culturally accepted questionnaire that was designed to be applicable to a broad spectrum of cancer patients as a core questionnaire. It is classified into 15 domains including five functional subscales (physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning); three multi-item symptom subscales (fatigue, nausea/vomiting, and pain); a global QOL subscale; and six single items addressing various symptoms and perceived financial impact.[11] All EORTC QLQ-C30 items use a four-point Likert scale (ie, "not at all," "a little," "quite a bit," and "very much"), except the two items assessing global QOL (item 29 and item 30), which use a seven-point scale.

Karnofsky Performance Scale (KPS)

The KPS, which is used to measure performance status, is an evaluation based on the observations of physicians. The health condition of patients is evaluated using a total score of 100 that is based on three aspects: daily activities, state of illness, and degree of personal care. The Karnofsky score runs from 100 to 0, where 100 is "perfect" health and 0 is death. Practitioners occasionally assign performance scores in between standard intervals of 10.

Investigation and statistical analyses

The participating investigators were nurses on duty in relevant departments, who had already been trained to do the investigation. The investigators explained the trial and scale to the patients and obtained basic information and KPS scores from those who agreed to participate in the study and met the inclusion criteria. Each participant answered the EORTC QLQ-CX24 and EORTC QLQ-C30 independently.

Descriptive statistics were used to analyze sociodemographic and clinical data. Internal consistency reliability was determined by Cronbach's α coefficient for each dimension, and $\alpha \geq 0.7$ indicated adequate scale reliability. The scale structure was evaluated by multitrait scaling analysis. The convergent validity for each scale was evaluated by assessing the Pearson's correlation coefficient between each item and its own scale, while the discriminant validity was examined by comparing the Pearson's correlation coefficient of each item with other scales. Scaling errors were defined as cases in which an item correlated significantly less with its own scale than with other scales. Difference of EORTC QLQ-CX24 scores in different International Federation of Gynecology and Obstetrics (FIGO)[12] stages (stage I vs stages II–IV) was analyzed by Mann–Whitney *U* test, and a *P*-value of <0.05 was considered statistically significant. Acceptability was evaluated through the accomplishment ratio of questionnaires, missing ratio of each item, and mean time of answering questionnaires. All data were analyzed with SPSS software (v 17.0; IBM Corporation, Armonk, NY, USA).

Ethics

This study was approved by the institutional review board of the First Affiliated Hospital of Xinxiang Medical University. Before the survey, participants were asked to sign informed consent to identify their willingness to take part in this study and to ensure their rights of voluntary participation and privacy.

Results

Sociodemographic characteristics

Baseline sociodemographic characteristics for the 115 cervical cancer patients are shown in Table 1. The mean age of participants was 44.8 ± 9.0 years. One hundred ten (95.7%) patients were of Han nationality and the remaining five (4.3%) patients were of other nationalities. Of all participants, 110 (95.7%) were married. Eighty (69.6%) patients had finished high school at most, and 30 (26.1%) patients held a bachelor's degree. A diagnosis of FIGO stage I disease had been made in 72 (62.6%) patients, and the remaining 43 (37.4%) patients were diagnosed in stages II–IV.

Table 1 Demographic and clinical characteristics of cervical cancer patients (n=115)

Characteristic	No of patients	%
Age (years)		
Mean ± SD	44.8 ± 9.0	
Nationality		
Han	110	95.7
Other	5	4.3
Marriage status		
Married	110	95.7
Not married	5	4.3
Employment status		
Employed	75	65.2
Unemployed	40	34.8
Educational status		
High school at most	80	69.6
Undergraduate	30	26.1
Other	5	4.3
Fertility status		
Has children	110	95.7
Has no children	5	4.3
Lives together with husband		
Yes	101	87.8
No	14	12.2
Treatment		
Surgery only	72	62.6
Surgery + radiotherapy	22	19.1
Surgery + chemotherapy	15	13.0
Surgery + radiotherapy + chemotherapy	6	5.2
FIGO stage		
Stage I	72	62.6
Stages II–IV	43	37.4
Climacteric status while receiving treatment		
Climacterium	25	21.7
Childbearing period	42	36.5
Post-menopause (age-related)	24	20.9
Post-menopause (treatment-related)	23	20.0
Unknown	1	0.9

Abbreviations: FIGO, International Federation of Gynecology and Obstetrics; SD, standard deviation.

Validity and reliability

Multitrait scaling analyses

Results for multitrait scaling analysis are shown in Table 2. Although the symptom experience scale exhibited three (3.4%) scaling errors, the scale evidenced good item-convergence (r =0.14–0.84) as well as item-discriminance (r =0.00–0.78). The body image and sexual/vaginal functioning scales exhibited 100% item-convergence (r =0.82–0.87 and 0.70–0.86, respectively) and 100% item-discriminance (r =0.03–0.76 and 0.00–0.30, respectively).

Relationship between the EORTC QLQ-C30 and the EORTC QLQ-CX24

The symptom experience, body image, menopausal symptoms, and peripheral neuropathy scales correlated strongly with the EORTC QLQ-C30 functioning scales (r =0.823, 0.724, 0.762 and 0.739, respectively). The peripheral neuropathy scale correlated strongly with the physical functioning, emotional functioning, and cognitive functioning scales. Meanwhile, scales related to sexuality (the sexual/vaginal functioning, sexual worry, and sexual enjoyment scales) correlated weakly with the EORTC QLQ-C30 (r <0.4), except for a moderate correlation between the sexual activity scale and EORTC QLQ-C30 (r =0.524) (Table 3).

Comparisons between KPS scores of EORTC QLQ-CX24 in different FIGO stages

All patients were divided into two groups based on their FIGO stage: early cervical cancer (stage I) and progressive cervical cancer (stage II–IV). As shown in Table 4, only the menopausal symptom scale was capable of discriminating among patients with different FIGO stages (P=0.018). No significant difference of scores for patients with different FIGO stages was found in other scales of the EORTC QLQ-CX24 (P>0.05). Results differed significantly among patients in early-stage (stage I) and advanced-stage (stages II–IV) with regard to peripheral neuropathy, menopausal symptoms, sexual activity, and sexual worry scales. Scores of the peripheral neuropathy and menopausal symptoms scales for patients with progressive cervical cancer were higher than for those with early cervical cancer, suggesting that correlative symptoms were much more obvious with the progression of

Table 2 Multitrait scaling analyses with Pearson correlations between scale items on EORTC QLQ-CX24

Scale/items	Item no	Mean ± SD	Cronbach's α	Item/own scale correlation	Item/other scale correlation	Scaling error (%)
Symptom experience	31–37, 39, 41–43	9.62 ± 10.48	0.82	0.14–0.84	0.00–0.78	3 (3.4)
Body image	45–47	16.43 ± 21.04	0.80	0.82–0.87	0.03–0.76	0 (0)
Sexual/vaginal functioning	50–53	17.14 ± 19.41	0.78	0.70–0.86	0.00–0.30	0 (0)
Lymphedema	38	7.25 ± 17.00	NA	NA	0.03–0.63	NA
Peripheral neuropathy	40	17.40 ± 19.42	NA	NA	0.02–0.61	NA
Menopausal symptoms	44	20.17 ± 23.72	NA	NA	0.22–0.57	NA
Sexual worry	48	11.60 ± 28.97	NA	NA	0.02–0.37	NA
Sexual activity	49	28.63 ± 35.98	NA	NA	0.02–0.37	NA
Sexual enjoyment	54	38.46 ± 28.30	NA	NA	0.03–0.50	NA

Note: Cronbach's $\alpha \geq 0.7$ indicates adequate scale reliability.
Abbreviations: EORTC QLQ-CX24, European Organization for Research and Treatment of Cancer Quality of Life questionnaire cervical cancer module; NA, not applicable; SD, standard deviation.

cervical cancer. Meanwhile, the significantly lower scores of the sexual activity and sexual worry scales for patients in progressive stage compared to patients in early stage indicated that sexual activity decreased and sexual worry increased with the development of cervical cancer (data not shown).

Acceptability

The two questionnaires were easily understood, with moderate compliance, which was likely due to the importance of privacy to the women. No missing value existed in the symptom experience, body image, lymphedema, and

Table 3 Pearson correlations between the EORTC QLQ-C30 and the EORTC QLQ-CX24

EORTC QLQ-C30	EORTC QLQ-CX24								
	Symptom experience	Body image	Sexual/ vaginal functioning	Lymphedema	Peripheral neuropathy	Menopausal symptoms	Sexual worry	Sexual activity	Sexual enjoyment
Functioning scales									
Physical functioning	–0.716**	–0.615**	0.009	–0.564**	–0.427**	–0.512**	0.005	0.310**	0.309**
Role functioning	–0.573**	–0.428**	0.092	–0.340**	–0.714**	–0.425**	0.175	0.323**	0.244**
Emotional functioning	–0.738**	–0.654**	0.012	–0.793**	–0.636**	–0.662**	0.001	0.202*	–0.053
Cognitive functioning	–0.824**	–0.573**	–0.026	–0.707**	–0.654**	–0.673**	0.012	0.281**	0.187*
Social functioning	–0.572**	–0.724**	0.031	–0.604**	–0.336**	–0.473**	0.097	0.363**	0.102
Global QOL	–0.553**	–0.583**	–0.036	–0.584**	–0.467**	–0.516**	0.027	0.524**	0.383**
Symptom scales									
Fatigue	0.632**	0.347**	0.036	0.515**	0.482**	0.506**	0.205*	–0.220*	–0.125
Nausea/ vomiting	0.156	0.443**	0.109	0.511**	–0.069	0.371**	–0.057	–0.206*	0.152
Pain	0.823**	0.549**	–0.004	0.551**	0.739**	0.603**	–0.086	–0.292**	–0.032
Single-item scales									
Dyspnea	0.660**	0.375**	–0.008	0.467**	0.532**	0.483**	0.138	–0.213*	–0.202*
Insomnia	0.558**	0.442**	0.000	0.518**	0.466**	0.762**	–0.240**	–0.374**	–0.158
Appetite loss	0.271**	0.590**	0.004	0.461**	0.082	0.425**	–0.175	–0.437**	–0.020
Constipation	0.357**	0.180	–0.065	0.113	0.548**	0.506**	–0.198*	–0.169	–0.096
Diarrhea	0.434**	0.534**	0.139	0.546**	0.185*	0.083	0.512**	–0.006	0.119
Financial difficulties	0.367**	0.724**	–0.005	0.643**	0.435**	0.378**	–0.029	–0.328**	0.015

Notes: *Correlation is significant at the 0.05 level (<0.40 =weak correlation, 0.40–0.60 =moderate correlation, >0.60 =high correlation). **Correlation is significant at the 0.01 level (two-tailed).
Abbreviations: C30, core questionnaire; CX24, cervical cancer module; EORTC, European Organization for Research and Treatment of Cancer; QLQ, Quality of Life questionnaire; QOL, quality of life.

Table 4 Comparisons between Karnofsky Performance Scale scores of EORTC QLQ-CX24 in different FIGO stages

EORTC QLQ-CX24 scale	Mean ± SD		*P**
	FIGO stage I (n=72)	FIGO stage II–IV (n=43)	
Multi-item scales			
Symptom experience	9.64 ±10.07	9.58 ± 11.24	0.656
Body image	13.73 ± 19.06	20.93 ± 23.53	0.152
Sexual/vaginal functioning	15.36 ± 18.10	20.00 ± 21.53	0.458
Single-item scales			
Lymphedema	5.09 ± 14.44	10.85 ± 20.21	0.072
Peripheral neuropathy	15.28 ± 19.33	20.93 ± 19.28	0.104
Menopausal symptoms	16.43 ± 23.14	26.36 ± 23.66	0.018
Sexual activity	32.84 ± 38.84	24.17 ± 30.18	0.391
Sexual worry	13.89 ± 32.02	7.75 ± 22.81	0.405
Sexual enjoyment	35.35 ± 29.98	43.86 ± 24.98	0.338

Note: *Mann–Whitney *U* test.
Abbreviations: EORTC QLQ-CX24, European Organization for Research and Treatment of Cancer Quality of Life questionnaire cervical cancer module; FIGO, International Federation of Gynecology and Obstetrics; SD, standard deviation.

peripheral neuropathy scales. Seven (6.1%) patients did not complete the sexual activity scale; 58 (50.4%) patients did not complete the sexual enjoyment scale; and 52 (45.2%) patients did not complete the sexual/virginal functioning scale. The mean time (± standard deviation) needed to complete assessments was 8.06 ± 4.01 minutes.

Discussion

This study presents data from the translation and validation of the EORTC QLQ-C30 and the EORTC QLQ-CX24. It is the first study to perform a psychometric validation of the EORTC QLQ-CX24 in mainland China, wherein one-third of the world's new cases of cervical cancer occur annually. The evaluation of QOL has been proven to be the most essential method by which to examine therapeutic effects, and previous QOL evaluations for cervical cancer patients have been carried out in a number of countries.[7,9,14] The main reason why this study is important is the fact that the morbidity and survival rate of cervical cancer is increasing, which will lead to an increase in the need for tools able to assess QOL in those cervical cancer patients. What is more, the results show that the EORTC QLQ-C30 and the EORTC QLQ-CX24, with appropriate translation, are cross-culturally valid in countries with non-English-speaking populations.

Pearson correlation analyses confirmed the satisfactory convergent and discriminant validity of the EORTC QLQ-CX24. The internal consistency of the body image scale in this study (α =0.80) was in accordance with that in previous research (α >0.7),[7,8,13,14] excluding one study conducted in South Asia by Jayasekara et al (α =0.63).[9] Results of multitrait scaling analysis in our study only revealed scaling errors in the symptom experience scale, which was similar to findings in Jayasekara et al's research,[9] demonstrating that EORTC QLQ-CX24 presents satisfactory reliability as well as convergent and discriminant validity in the People's Republic of China.

As Table 4 shows, only the menopausal symptoms scale in EORTC QLQ-CX24 was able to distinguish patients in different FIGO stages. Quite different results were obtained by Greimel et al[8] – a difference that may result from diverse attitudes toward sexuality in Eastern and Western countries. Chinese patients with cervical cancer tend to avoid talking about sexuality, so scales related to sexuality do not differentiate patients in different FIGO stages in the People's Republic of China. Another explanation might be the fact that, during the interviews, a significant group of patients seemed to focus mainly on the fact of having cancer and not on the FIGO stages. These two reasons might have made it hard for EORTC QLQ-CX24 to distinguish patients in different stages.

Correlations between the QLQ-C30 and the QLQ-CX24 were strong in some scales, which signifies clinical overlap, and weak or absent in others, which signifies differences due to the fact that both instruments assess different aspects of QOL. There is no point in using the EORTC QLQ-CX24 if the two questionnaires correlate strongly in every item, meaning that the same aspect of QOL is evaluated. These results support the EORTC statement that the questionnaires have to be used together to fully assess the QOL in patients.[8]

The EORTC QLQ-CX24 proved to be patient-friendly, as evidenced by the high response rate of the study and acceptable rate of missing values. In fact, most patients welcomed the opportunity to report their health and illness experiences in detail, especially during the acute phase of their disease, perhaps to compensate for the little time they get to communicate with health care providers in the local system. There are two optional scales – sexual/vaginal functioning and sexual enjoyment – that can be skipped if the woman considers herself to have been not sexually active during the past 4 weeks. These scales, therefore, had a higher missing value rate than the others (50.4% and 45.2%, respectively). Other missing values for non-optional items occurred only in the sexuality scales. Similar missing values were found in foreign studies, especially in South Korea, which may due to the privacy of sexuality.[2] Although patients may wish to know their physical status and assist doctors in selecting proper therapy, there remains a strong tendency to maintain sexual privacy, especially in Asian women. In order to evaluate the

QOL of patients exactly, detailed interpretation of security and sexuality for patients when disseminating questionnaires is of great importance.

Prior to our study, only two papers related to the QOL of cervical cancer patients in mainland China were published, which used the Functional Assessment of Cancer Therapy-Cervix (FACT-Cx) questionnaires.[15,16] The use of FACT-Cx is more popular in the United States. Whether to favor the EORTC QLQ-CX24 or FACT-Cx in clinical practice is still in dispute.[17]

Conclusion

The satisfactory participation rate indicates that the Chinese version of the EORTC QLQ-CX24 questionnaire possesses ideal acceptability, and results of Cronbach's α coefficients, Pearson correlation test, and Mann–Whitney *U* test support good validity and reliability. Our results indicate that the Chinese version of the EORTC QLQ-CX24 questionnaire can be used as a reliable and efficient instrument in clinical research to study the QOL of Chinese patients with cervical cancer.

Disclosure

The authors report no conflicts of interest in this work.

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