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Psychometric validation of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Endometrial Cancer Module (EORTC QLQ-EN24)

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ABSTRACT

Aim: A validation study was conducted to evaluate the psychometric properties of the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Endometrial Cancer Module (EORTC QLQ-EN24). This module was designed to assess disease and treatment specific aspects of the quality of life (QoL) of patients with endometrial cancer.

Methods: Two hundred and sixty-eight women with endometrial cancer were recruited in different phases of treatment: after pelvic surgery (Group 1); during adjuvant chemotherapy and/or radiotherapy (Group 2); after completion of treatment (Group 3). Patients completed the EORTC QLQ-C30, the endometrial cancer module and a short debriefing questionnaire.

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Results: Multi-trait scaling analyses confirmed the hypothesised scale structure of the QLQ-EN24. Internal consistency reliability was good with Cronbach's alpha coefficients ranging from 0.74 to 0.86 (lymphoedema 0.80, urological symptoms 0.75, gastrointestinal symptoms 0.74, body image problems 0.86 and sexual/vaginal problems 0.86). Convergent and discriminant validity did not show any scaling errors for the subscales. The QLQ-EN24 module discriminated well between clinically different groups of patients. All items exhibited a high completion rate with less than 2% missing values except for the sexuality items (19%).

Conclusion: The validation study supports the reliability, the convergent and divergent validity of the EORTC QLQ-EN24. This newly developed QLQ-EN24 module is a useful instrument for the assessment of the QoL in patients treated for endometrial cancer in clinical trials.

1. Introduction

In developed countries, incidence rates of endometrial cancer have arisen due to a combination of factors that include an ageing of the population, increased obesity and exposure to exogenous oestrogens.[1] Endometrial cancer often causes vaginal bleeding as an early symptom and is usually diagnosed in an early stage. Effective treatment of early stage disease is achieved by surgery alone. In general, the survival for early stage endometrial cancer is high. However 15% of the patients are present with advanced disease. The relapse rate varies from less than 5% for low risk cases to almost 30% for high risk patients.[2,3] There remains uncertainty as to the value of extensive surgical staging including pelvic and para-aortic lymphadenectomy and the benefits versus side-effects of adjuvant pelvic radiotherapy and systemic chemotherapy for high risk cases.[2,3] Current multicenter research efforts aim to identify high risk patients who may benefit from post-operative radiation with or without chemotherapy and to establish the most effective combination of adjuvant therapies.[4]

Studies investigating the symptom burden in patients with endometrial cancer have highlighted issues related to treatment, both by surgery and radiotherapy. The symptoms comprise psychological morbidity[5] as well as physical morbidity[6–9] including late urological and gastrointestinal symptoms following radiotherapy.[10,11] For endometrial cancer patients there is a lack of specific measures that detect the disease and treatment related quality of life (QoL) issues. Herein, we present the first international field study with cross-cultural validity results of a cancer site-specific QoL measure for women with endometrial cancer. The endometrial cancer module was developed in accordance with the European Organisation for Research and Treatment of Cancer (EORTC) guidelines for module development.[12–14] This process involves four phases: generation of relevant QoL issues (phase 1), operationalisation into questionnaire items (phase 2), pre-testing the provisional questionnaire module (phase 3) and testing the psychometric properties in a cross-cultural field study (phase 4). The aim of the present study was to test the hypothesised scale structure, the reliability and the validity of the module designed to be used in conjunction with the QLQ-C30.

2. Patients and methods

2.1. Measurements

Patients in different countries completed the EORTC QLQ-C30[15] and the respective translations of the endometrial cancer module following the EORTC guidelines for developing questionnaire modules.[13] In addition a short debriefing questionnaire was used that asked patients to indicate the time taken to complete the questionnaires, the need for assistance in completing them and whether any of the items were confusing, difficult to answer or upsetting. The Karnofsky performance status (KPS) scale was rated by the treating physician. Socio-demographical data were collected on case report forms. Disease and treatment related information was collected from the medical charts.

2.2. Patients and data collection schedule

For the field study a heterogeneous sample of women with endometrial cancer undergoing a variety of treatments were recruited between May 2008 and June 2009. Patients were eligible if they had a histological-confirmed diagnosis of endometrial cancer in any stage according to the International Federation of Gynaecology and Obstetrics (FIGO) system, no previous or concurrent cancer, were mentally fit to complete questionnaires and were able to understand the language of the questionnaire. Written informed consent was obtained from all patients. Patients recruited from 13 hospital centres in Europe, Australia and Asia was treated according to national or local guidelines. The institutional review board or ethical committee at the investigators' hospital and/or the national ethical committee reviewed and approved the study. As the aim was to develop a questionnaire to be used in different phases of the disease, we included three groups: Group 1 consisted of patients who had pelvic surgery without adjuvant treatment. They completed the QLQ-C30 and the module 7 d to 3 months after the surgery. Group 2 included patients during adjuvant treatment (chemotherapy and/or radiotherapy). These patients completed the questionnaires during therapy (on the day of the third cycle of chemotherapy and 3–6 weeks after the first radiation). Group 3 included patients who had completed any treatment more than 3 months ago.

They completed the questionnaires twice: 3 months after completion of the treatment and then again 3–7 d later. This group was selected for test–retest as they were not expected to show any changes in health status since they were off-treatment.

2.3. Statistical analysis

Data were analysed using Statistical Package for the Social Sciences (SPPS). The sample size calculation was based on the recommendation by Tabachnik and Fidell[16] that five to ten patients per questionnaire item are required for multivariable analyses in order to generate stable reliability and validity estimates (recruitment target 10 patients × 24 = 240 patients). A total of 268 patients were enrolled.

2.3.1. Scoring

The scores of the QLQ-C30 and QLQ-EN24 were linearly transformed to a 0–100 scale according to the scoring manual of the EORTC Quality of Life Group.[17] Higher QLQ-C30 scores on the functioning scale and the global QoL scale indicated better functioning or QoL, whereas higher scores on the symptom scales represented a higher level of symptoms or problems in both the QLQ-C30 and the QLQ-EN24. A higher score on items related to sexuality (sexual interest, sexual activity and sexual enjoyment) in the QLQ-EN24 module indicated better sexual functioning. Some items related to sexuality were optional and required being sexually active. For these items only scores from eligible respondents were computed. Mean scores and standard deviations (SD) were calculated for the multi-item and single-item scales.

2.3.2. Multi-trait scaling analysis

Multi-trait scaling analyses were employed to examine whether the individual items of the QLQ-EN24 could be aggregated into a more limited set of multi-item scales.[18] Evidence of item convergent validity was defined as a correlation of $\geqslant$0.40 between an item and its own scale (corrected for overlap).[19] Support for item discriminant validity was based on the correlation between an item and its own scale as compared with other scales. A scaling success was counted when the item correlation to its own scale was significantly higher than the correlations of the item to other scales. A scaling error was counted when the correlation between an item and its own scale was lower than its correlation with any other scale.

2.3.3. Reliability

Reliability of the multi-item scales was assessed with Cronbach's alpha coefficient. Internal consistency estimates of $\geqslant$0.70 were considered acceptable for group comparisons.[19] Test–retest reliability was assessed using Pearson's correlations between the first and the second assessments.

2.3.4. Validity

Convergent and divergent validity was examined by evaluating Pearson's product moment correlations between the various scales of the EORTC QLQ-C30 and the module. It was expected that scales that are conceptually related correlate substantially with one another ($r \geqslant 0.40$). Conversely, scales with a less conceptual overlap are expected to exhibit lower correlations ($r < 0.40$).[19]

2.3.5. Known-group comparisons

The method of known-group comparisons was used to explore the extent to which the scale scores were able to

Table 1 – Socio-demographical and clinical characteristics of the sample (*N* = 268).

Age (years), mean (SD), range 35.4–87.8	64.5 (9.65)
Country	%
Australia	8.6
Austria	10.1
Croatia	4.5
Denmark	8.2
Germany	10.1
Italy	2.2
The Netherlands	14.2
Sweden	7.5
Taiwan	7.1
United Kingdom	27.6
Education level	
Less than compulsory school education	10.8
Compulsory school education	50.4
Post compulsory education below university level	31.3
University level	7.5
Employment status	
Full time	16.5
Part time	8.3
Retired/homemaker	75.2
Cohabitants	
Living alone	27.1
Living with partner	56.5
Living with others (children and relatives)	16.4
Sexual partner	
No	46.7
Yes	53.3
Stage of disease (FIGO)	
Stage I	56.2
Stage II	18.5
Stage III	21.1
Stage IV	4.2
Menopausal status	
Pre-menopausal	12.3
Post-menopausal	85.4
Unknown	2.2
Comorbidity	
No	50.4
Yes	49.6
Treatment	
Surgery only	34.0
Adjuvant radiotherapy	38.4
Adjuvant chemotherapy	14.6
Adjuvant chemoradiation	13.1
Treatment status	
After surgery	15.7
During adjuvant treatment	33.0
Post-treatment	51.3
Karnofsky performance status (KPS) Mean (SD)	90.0 (10.95)

Table 2 – Item correlations within scale and item correlations with other scales.

Scale	Number of items	Mean	SD	Cronbach's alpha	Item-own scale correlations[a]	Item-other scale correlations	N (%) scaling errors
LY Lymphoedema Items 31, 32	2	20.8	26.5	0.80	0.67–0.67	−0.12–0.39	0 (0.0%)
UR Urological symptoms Items 34–37	4	21.9	21.4	0.75	0.40–0.66	−0.08–0.39	0 (0.0%)
GI Gastrointestinal symptoms Items 38–42	5	18.6	18.8	0.74	0.43–0.60	−0.13–0.37	0 (0.0%)
BI Body image problems Items 47, 48	2	13.3	22.6	0.86	0.75–0.75	−0.12–0.32	0 (0.0%)
SV Sexual/vaginal problems Items 51–53	3	22.8	27.9	0.86	0.66–0.84	−0.24–0.22	0 (0.0%)
BP Back/pelvic pain Item 33	1	25.6	29.6	n.a.	n.a.	−0.19–0.42	n.a.
TN Tingling/numbness Item 43	1	20.4	26.8	n.a.	n.a.	−0.15–0.36	n.a.
MJ Muscular/joint pain Item 44	1	26.5	30.0	n.a.	n.a.	−0.03–0.42	n.a.
HL Hair loss Item 45	1	13.2	30.6	n.a.	n.a.	−0.07–0.36	n.a.
TC Taste change Item 46	1	11.0	24.4	n.a.	n.a.	−0.17–0.33	n.a.
SXI Sexual interest Item 49	1	14.2	20.8	n.a.	n.a.	−0.14–0.67	n.a.
SXA Sexual activity Item 50	1	11.0	19.7	n.a.	n.a.	−0.17–0.67	n.a.
SXE Sexual enjoyment Item 54	1	56.0	29.2	n.a.	n.a.	−0.21–0.52	n.a.

% Floor, percentage of respondents at the lowest rating.
% Ceiling, percentage of respondents at the lowest rating.
[a] Corrected for overlap, n.a. not available.

discriminate between subgroups of patients who differed in terms of their clinical status.[20] The clinical parameters employed to form mutually exclusive patient subgroups included Karnofsky performance status (KPS) at the time of the assessment. We compared patients with a KPS score of >80 indicating a good performance status with patients scoring ⩽80 indicating a poor performance status. Concerning treatment status we compared patients after surgery (Group 1), patients during adjuvant treatment (Group 2) and patients post-treatment (Group 3). *T*-tests for independent samples were performed to test for group differences.

3. Results

3.1. *Patient characteristics*

A total of 268 patients with endometrial cancer were recruited. Socio-demographical and clinical characteristics are shown in Table 1. The patients' age ranged from 35.4 to 87.8 years (mean 64.5 years). The sample included patients from eight European countries, Australia and Taiwan. More than half of the patients had stage I disease (56.2%), almost half had significant comorbidity (49.6%) and 85% were menopausal. Almost all

Table 3 – Correlations between EORTC QLQ-C30 and QLQ-EN24.

EORTC QLQ-C30	LY	UR	GI	BI	SV	BP	TN	MP	HL	TC	SXI	SXA	SXE
Physical functioning	−0.29**	−0.26**	−0.32**	−0.26**	−0.13	−0.39**	−0.11	−0.25**	−0.08	−0.37**	0.18*	0.11	0.28
Role functioning	−0.18*	−0.21**	−0.24**	−0.33**	−0.29	−0.28**	−0.02	−0.15	−0.04	−0.41**	0.20*	0.18*	0.22
Emotional functioning	−0.26**	−0.33**	−0.27**	−0.30**	−0.32	−0.26**	−0.20*	−0.25**	−0.13	−0.29**	0.12	0.01	0.42*
Cognitive functioning	−0.21**	−0.36**	−0.24**	−0.45**	−0.44*	−0.29**	−0.21**	−0.23**	−0.17*	−0.36**	0.18*	0.15	0.20
Social functioning	−0.24**	−0.27**	−0.30**	−0.41**	−0.35	−0.26**	−0.08	−0.16*	−0.12	−0.47**	0.18*	0.19*	0.28
Global QoL/health status	−0.29**	−0.29**	−0.35**	−0.30**	−0.20	−0.31**	−0.11	−0.24**	−0.10	−0.35**	0.29**	0.26**	0.25
Fatigue	0.30**	0.27**	0.35**	0.43**	0.33	0.32**	0.20**	0.21**	0.20**	0.54**	−0.18*	−0.13	−0.23
Nausea/vomiting	0.09	0.10	0.17*	0.32**	−0.06	−0.02	0.12	0.12	0.22**	0.34**	−0.13	−0.09	−0.01
Pain	0.22**	0.14	0.38**	0.15	0.04	0.57**	0.26**	0.36**	0.09	0.41**	−0.22**	−0.15	−0.12
Dyspnoea	0.34**	0.32**	0.19*	0.32**	0.04	0.12	0.23**	0.13	0.24**	0.17*	−0.14	−0.08	−0.27
Sleep/insomnea	0.27**	0.32**	0.34**	0.36**	0.09	0.17*	0.17*	0.15	0.21**	0.29**	−0.16*	−0.18*	−0.53**
Appetite loss	0.12	0.11	0.27**	0.14	−0.07	0.26**	0.08	0.06	0.07	0.62**	−0.20*	−0.18*	−0.23
Constipation	0.05	−0.03	0.20*	0.14	−0.10	0.06	0.07	−0.02	0.34**	0.25**	−0.12	−0.11	−0.54**
Diarrhoea	0.22**	0.24**	0.51**	0.13	−0.11	0.08	0.26**	0.11	0.09	0.15	−0.02	0.00	0.19
Financial difficulties	0.12	0.19*	0.16*	0.34**	0.13	−0.02	0.14	0.21**	0.25**	0.07	−0.18*	−0.13	0.20

<0.40 = Weak correlation, 0.40–0.60 = moderate and >60 = high.

* $p < 0.05$.

** $p < 0.01$ (two-tailed).

the patients had undergone surgery as part of the primary treatment for endometrial cancer, 38.4% had adjuvant radiotherapy and 14.6% had adjuvant chemotherapy. The KPS scores were high, with a mean score of 90.

3.2. *Completion rates and questionnaire acceptability*

The majority of patients (89%) completed the EORTC QLQ-C30 and the QLQ-EN24 in less than 15 min and did not require any assistance to complete the questionnaires (88%). Most patients found that the questions were clear (89%) and not upsetting (95%). No items were reported to be confusing or upsetting by more than 2% of the patients. All the items exhibited had a good completion rate with less than 2% of the missing values except the items related to sexuality (19%). These items generated more frequent critical comments than the other items. The sexuality items were only completed by patients who were reported to be sexually active at the time of assessment (26%).

3.3. *Multi-trait scaling analysis*

All item-scale correlations for the multi-item scales exceeded the 0.40 criterion and correlated much higher with their own scale (0.40–0.84) than with the other scales (0.08–0.39). There were no scaling errors of the hypothesised scales (Table 2). The scaling analyses confirmed five multi-item scales with acceptable Cronbach's alpha coefficients ranging from 0.74 to 0.86. The chemotherapy related items assessed specific and largely independent treatment-related side-effects and the alpha coefficient was low (0.59). Therefore, these items were kept as single-item scales.

The psychometric property of the hypothesised scale for sexual functioning was poor when including vaginal symptoms and sexual functioning items in one scale. The proposed sexual functioning scale intuitively appeared to be a heterogeneous aggregation of items related to sexuality and vaginal symptoms, rather than a single measure of sexual functioning. Therefore, three items related to sexual functioning were

Table 4 – Differences in the EORTC QLQ-EN24 scales by treatment and performance status.

QLQ-EN24 scales	No chemotherapy N = 202		Chemotherapy N = 66		*p*	Karnofsky ⩽ 80 N = 70		Karnofsky > 80 N = 189		*p*
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Lymphoedema	17.2	24.4	29.8	30.5	0.001	28.6	30.7	17.1	23.9	0.002
Urological symptoms	20.5	20.3	26.4	24.1	0.051	27.9	24.8	19.2	19.2	0.003
Gastrointestinal symptoms	18.2	190	20.4	18.4	0.418	24.9	20.2	15.8	17.4	<0.001
Body image problems	10.6	19.9	21.7	27.4	0.000	22.4	30.2	10.1	18.4	<0.001
Sexual/vaginal problems	22.0	28.1	26.3	28.2	0.652	33.3	35.8	20.1	25.0	0.251
Back/pelvis pain	25.0	28.6	27.3	32.5	0.596	41.4	35.2	20.0	25.2	<0.001
Tingling/numbness	13.9	19.8	40.4	34.9	0.000	24.3	31.0	18.7	24.6	0.133
Muscular/joint pain	24.1	28.1	33.8	34.3	0.021	33.3	35.4	24.3	27.2	0.031
Hair loss	4.5	15.9	39.4	46.4	0.000	13.0	29.8	12.6	30.5	0.915
Taste change	6.4	19.0	25.1	32.8	0.000	20.5	35.1	6.7	16.1	<0.001
Sexual interest	15.8	21.6	9.4	17.3	0.032	8.6	17.8	16.0	21.00	0.011
Sexual activity	12.1	20.6	7.7	16.4	0.123	6.3	15.6	12.4	20.6	0.030
Sexual enjoyment	54.6	28.8	61.1	31.3	0.495	38.9	32.8	56.7	28.6	0.162

Table 5 – Differences in the EORTC QLQ-EN24 scales by treatment status.

QLQ-EN24 scales	After surgery (N = 43)		During adjuvant treatment (N = 88)		Post treatment (N = 137)		p
	Mean	SD	Mean	SD	Mean	SD	
Lymphoedema	16.27	23.13	19.23	24.56	21.29	27.40	0.539
Urological symptoms	19.78	21.29	26.55	23.05	21.72	20.55	0.254
Gastrointestinal symptoms	17.54	16.57	22.83	21.13	16.79	17.88	0.130
Body image problems	19.84	28.33	15.71	26.07	9.49	19.05	0.021
Sexual/vaginal problems	37.04	33.95	28.40	25.53	21.35	27.26	0.536
Back/pelvis pain	22.22	26.20	27.56	32.82	25.00	27.74	0.668
Tingling/numbness	5.56	12.57	30.77	32.23	19.71	25.10	0.000
Muscular/joint pain	16.67	23.57	18.59	25.06	31.14	29.76	0.002
Hair loss	3.25	14.54	30.77	42.19	8.33	24.26	0.000
Taste change	11.11	25.15	18.59	33.28	4.66	14.73	0.001
Sexual interest	11.40	23.60	8.33	14.59	18.86	21.99	0.006
Sexual activity	8.77	21.48	6.38	13.26	14.36	21.54	0.042
Sexual enjoyment	77.78	38.49	33.33	28.87	58.97	27.00	0.023

Note. Different letters indicate statistically significant mean differences at 0.05 (Tukey's HSD).

kept as single item scales (sexual interest, sexual activity and sexual enjoyment) and the items related to vaginal symptoms and pain during sexual activity were retained as a multi-item scale. Test–retest reliability resulted in correlations ranging from 0.81 to 0.92 for the multi-item scales (lymphoedema 0.87, urological symptoms 0.92, gastrointestinal 0.81, body image 0.84 and sexual/vaginal symptoms 0.88) and from 0.72 to 0.97 for the single-item scales (back/pelvic pain 0.88, tingling/numbness 0.72, muscular/joint pain 0.87, hair loss 0.97, taste change 0.85, sexual interest 0.84, sexual activity 0.83 and sexual enjoyment 0.77).

3.4. *Validity*

Most scales of the QLQ-EN24 were weakly correlated with the QLQ-C30 scales ($r < 0.40$) (Table 3). Correlations between body image problems and cognitive functioning ($r = -0.45$), social functioning ($r = -0.41$) and fatigue ($r = 0.43$) were slightly above 0.40, but still weak. The correlation between sexual/vaginal symptoms and cognitive functioning was −0.44. The item on back/pelvic pain in the QLQ-EN24 was moderately correlated with the pain scale in the QLQ-C30 ($r = 0.57$). A similar correlation was found for the item diarrhoea in the QLQ-C30 and the gastrointestinal symptom scale in the QLQ-EN24 ($r = 0.57$). The highest correlation was found for taste change and loss of appetite ($r = 0.62$). Taste change correlated moderately with pain ($r = 0.41$), role functioning ($r = -0.41$), social functioning ($r = -0.47$) and fatigue ($r = 0.54$). Sexual enjoyment was also moderately correlated with emotional functioning ($r = 0.42$), sleep ($r = -0.53$) and constipation ($r = 0.54$).

3.5. *Known-group comparisons*

Patients with a KPS score of $\leqslant 80$ had significantly higher scores on four multi-item scales (lymphoedema, urological symptoms, gastrointestinal symptoms and body image problems). On the single item level back/pelvic pain, muscular/joint pain and taste change were significantly more severe in patients with a lower performance status. Concerning single items on sexuality, patients with a KPS score of $\leqslant 80$ had significantly lower scores on the sexual interest and sexual activity scale compared to patients with a KPS score of >80. There was no difference concerning sexual/vaginal problems, sexual enjoyment, tingling/numbness and hair loss. Women undergoing chemotherapy reported significantly more problems with lymphoedema, body image, tingling/numbness, muscular pain, hair loss and taste change than those who did not receive chemotherapy. Further, on the sexual interest scale they showed significantly lower scores compared to patients in the non-chemotherapy group (Tables 4 and 5).

Concerning treatment status, patients after treatment (post-treatment group) had significantly lower body image problems compared to patients after surgery. Patients during adjuvant treatment had significantly more problems with tingling and numbness, hair loss and taste change compared to patients after surgery and patients who had completed the treatment. Muscle and joint pain were significantly higher in post-treatment patients compared to patients under adjuvant treatment and patients after surgery. Concerning sexuality the level of interest and activity was lowest during adjuvant treatment. Sexual enjoyment was highest in patients after surgery compared to patients undergoing adjuvant treatment or post-treatment.

4. Discussion

The QLQ-EN24 module was developed to assess the QoL of patients with endometrial cancer. This study demonstrated the validity, the reliability and the test–retest reliability of the module in an international sample of women with endometrial cancer. The content- and face validity has been ensured through a well-defined guideline developmental process. This included a comprehensive literature review to extract relevant issues for conceptualisation, expert advising from the EORTC Gynaecological Cancer Group, patient and health care providers' interviews and several multidisciplinary cross-cultural expert panel discussions.

Reliability estimates indicated a high internal consistency of most of the multi-item scales. However, the Cronbach's alpha coefficients for the chemotherapy scale and the sexual

functioning scale were poor. The items related to chemotherapy-assessed specific and largely independent side-effects. Therefore, it was decided to use these as single items. The proposed sexual functioning scale included vaginal problems and sexual interest, activity and enjoyment items. As a consequence of the scaling analyses the sexual/vaginal symptoms scale was separated and three items related to sexuality were kept as single items (sexual interest, sexual enjoyment and sexual activity). These items showed a high sensitivity to discriminate between distinct patient groups. It was therefore agreed to accept the new scale structure guided by the psychometric analyses and further discussions within the EORTC QoL group. It should be noticed that the QLQ-EN24 does not measure sexual functioning comprehensively but it includes important areas. Sexual interest increased significantly during treatment and post-treatment. However, in this study more than two thirds (74%) of the patients were not sexually active. Although sexually active women were not strongly represented in our study population, the instrument needs to be sensitive to these issues so that it can be used in trials of sexually active women in the future. Known-groups comparisons showed that sexual interest, sexual activity and sexual enjoyment discriminated well between treatment groups. Previous validation studies[21–23] showed high missing data rates on the sexuality items. In our study the main reason for not being sexually active was that almost half of the study participants did not have a sexual partner at the time of the assessment. Nevertheless, sexuality issues for endometrial cancer patients were rated as relevant and important by both patients and clinicians during the interviews and are of particular importance for sexually active women.

Overall, the results suggest that the QLQ-EN24 measures domains that are different from the QLQ-C30. Within the module, only two scales (muscular/joint pain and the back/pelvic pain) were correlated higher than 0.40. All other scales were weakly correlated, indicating that the scales measure independent areas of QoL within the QLQ-EN24. From a clinical point of view, patients with a high score on low back pain would most likely have a high general pain score as well. Low back pain is relevant for patients undergoing various treatments in the pelvic region. Preliminary clinical analyses verified that this particular item exhibited an ability to discriminate between patients who had lymphadenectomy and those who had not. Except for those described above, all the other scales and single items correlated as anticipated and, therefore, supported the convergent validity. The QLQ-EN24 scales discriminated well among patients in different stages of treatment. There is evidence that women treated for endometrial cancer, including women up to 3 months post-surgery and women more than 3 months after treatment across stages and grades continue to experience symptoms related to their cancer or its treatment. The PORTEC studies highlight the impact of external beam radiotherapy to the pelvis on the QoL, showing a significant long term negative impact on symptom and functional scales.[9]

In summary, the results of the present international field study support the psychometric robustness of the QLQ-EN24 module. The strength of the QLQ-EN24 is its' cross-cultural applicability and involvement of patients and professionals in all the developmental phases. Future clinical studies are needed to further investigate the responsiveness of the EORTC QLQ-EN24. On psychometric grounds the QLQ-EN24 module can be recommended as a supplement to the EORTC QLQ-C30 to measure the QoL of endometrial cancer patients in clinical trials. The development of the QLQ-EN24 has been documented and the reports for phase 1–4 were reviewed and approved by the EORTC Quality of Life Group Module Development Committee.[24] The QLQ-EN24 is already available from the Quality of Life Department at the EORTC data centre (www.eortc.be/home/qol) in nine languages (Croatian, Chinese/Mandarin, Danish, Dutch, English, German, Italian, Norwegian and Swedish).

Conflict of interest statement

None declared.

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