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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.