Validation of the Korean version of the EORTC QLQ-C30

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Abstract

This study evaluated the Korean version of the EORTC QLQ-C30 (version 3.0) in terms of psychometric properties and its validation. One hundred and seventy patients completed three questionnaires EORTC QLQ-C30, the Beck depression inventory (BDI), and a brief pain inventory (BPI). Multitrait scaling analyses demonstrated that all scales met multidimensional conceptualization criteria, in terms of convergence and discrimination validity. Cronbach’s α coefficients for eight multiple-item scales were greater than 0.70, with the exception of cognitive functioning. All interscale correlations were statistically significant in the expected direction (p < 0.01). Multivariate analyses showed that physical and emotional functioning were significant explanatory variables for the global quality-of-life (QOL) scale (regression coefficients: 0.36, p < 0.001; and 0.37, p < 0.001; respectively). All scales were significantly associated with pain severity and interference of the BPI, and with the cognitive-affective and somatic scales of the BDI. The emotional-functioning scale was substantially correlated with the cognitive-affective scale and somatic scale of the BDI. These results demonstrate that the Korean version of the EORTC QLQ-C30 is a valid instrument for evaluating Korean-speaking patients with cancer, and can be used to distinguish clearly between subgroups of patients of differing performance status.

Key words: BDI, BPI, EORTC QLQ-C30, Korea, Validation study

Introduction

There is an increasing need to assess the quality of life (QOL) experienced by patients as a result of cancer and its treatment in Korea. A variety of QOL assessment tools have been developed, with a particular focus on cancer patients. Incorporating QOL assessments in clinical trials research requires the selection of brief, reliable, and valid assessment tools for components such as physical functioning, emotional functioning, symptoms, and global QOL [1]. In 1986, the European Organization for Research and Treatment of Cancer (EORTC) initiated a research program to develop an integrated and modular approach for evaluating the QOL of patients participating in international clinical trials [2]. The validity of the EORTC QLQ-C30 has already been demonstrated in Iran and in Asian countries, including Japan and China. In Korea, many oncologists have also been interested in the QOL and need a QLQ (QOL questionnaire). The EORTC QLQ-C30 has been translated into Korean, but its applicability needs to be confirmed in Korean cancer patients with cross-cultural validation due to the unique language and culture.

This study evaluated the psychometric properties of the Korean version of the EORTC QLQ-C30 (version 3.0), with the aim of confirming the validation using the Beck depression inventory (BDI), the brief pain inventory (BPI), and the Eastern Cooperative Oncology Group Performance Status (ECOG PS).
Patients and methods

Study sample and protocol

Subjects for this study were recruited at three hospitals in Korea between July and November 2001. All the patients included were diagnosed with the pathology of cancer, were older than 18 years, and gave their informed consent. Patients were excluded if they were unable to complete the questionnaire due to serious physical or psychological morbidity. The patients were asked to complete the self-administered questionnaire either at the outpatient clinic or during their hospitalization. Their doctors were questioned as to the diagnosis, disease status, time since diagnosis, treatment, and ECOG PS.

Instruments used in the study

The EORTC QLQ-C30 is a 30-item core-cancer-specific questionnaire-integrating system for assessing the health-related QOL of cancer patients participating in international clinical trials [3]. The questionnaire incorporates five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea and vomiting), a global health and QOL scale, and single items for the assessment of additional symptoms commonly reported by cancer patients (e.g., dyspnea, appetite loss, sleep disturbance, constipation, and diarrhea), as well as the perceived financial impact of the disease and treatment [2]. All items are scored on 4-point Likert scales, ranging from 1 (‘not at all’) to 4 (‘very much’), with the exception of two items in the global health/QOL scale which use modified 7-point linear analog scales [3].

The Korean EORTC QLQ-C30 was developed by EORTC using a rigorous translation and backtranslation process. In order to identify and solve potential problems in the translation, the translated version was subsequently pilot tested by 14 patients recruited from the National Cancer Center in Korea. The patients’ comments lead to appropriate modifications to the questions and scales, after which it was reviewed and approved by the EORTC QOL Study Group. In the present study, the BDI and the BPI were used to compare subscales of the EORTC QLQ-C30. The BDI was originally designed to quantify the depth or intensity of depression in psychiatric patients [4, 5]; it evaluates 21 symptoms of depression that represent cognitive-affective content and somatic content [6]. Each symptom is rated on a 4-point scale, with the scores being added to give a total ranging from 0 to 63, where higher scores represent more severe depression [6, 7]. The BPI asks patients to rate their pain at its worst over the past day, where the intensity is recorded on numerical scales ranging from 0 (no pain) to 10 (pain as bad as you can imagine). The BPI asks for ratings of the degree to which pain interferes with general activity, mood, walking, normal work, relations with others, sleep, and enjoyment of life, using numeric scales ranging from 0 (‘no interference’) to 10 (‘interferes completely’) [6, 8, 9]. The worst pain of four severity items and the sum of seven pain interference items were used to compute the correlation with the pain scale of the EORTC QLQ-C30.

A range of statistical analyses was carried out to evaluate item discrimination validity, reliability and validity among the items and scales using correlation methods and comparisons of mean scores.

Results

Between July and November 2001, 170 cancer patients completed the questionnaires. The demographic characteristics of the 170 patients are listed in Table 1.

Multitrait scaling

The multitrait scaling analysis of the EORTC QLQ-C30 showed that all item-scale correlations were above 0.40. In terms of item-scale correlations, no scaling errors were found in any of the items. A multitrait scaling analysis [10] was conducted to test for item convergence and discrimination validity, and was based on the examination of correlation coefficients among the items and scales. The item convergence validity was available for a correlation above 0.40 between an item and its scale (corrected for overlap). The item discrimination validity was available for comparison of the magnitude of the correlation of an item with