instrument has five functional scales (physical, role, cognitive, emotional, and social) three symptom scales (fatigue, pain, and emesis), and a global health/quality of life scale. The remaining single items assess dyspnea, appetite loss, sleep disturbance, constipation, and diarrhea. The analyses focused on intraclass correlation coefficients (ICCs) in the range of 0.608 to 0.901. Lower confidence interval with a critical value of 0.70. RESULTS: Subjects who did not complete the second assessments within 72 hours or who had score differences on the scales or items exceeding two standard deviations were excluded from the per protocol analyses. The sample sizes used in the per protocol analyses ranged from 112 to 115 subjects. The ICCs for the 9 multi-item scales were all above 0.69, ranging from 0.698 to 0.926 (ICC 95% lower CI range: 0.608 to 0.901). All of the scales were significantly different from our threshold reliability of 0.70, with the exception of the cognitive functioning scale. The ICCs for the 6 symptom scales (fatigue, pain, and emesis) were 0.782 to 0.908 (ICC 95% lower CI range: 0.714 to 0.876) and all were statistically different from 0.70. The evidence supports the stability of the scores obtained on the IVR version of the QLQ-C30 upon repeated measurement.

Conclusions: The equivalence of the IVR and paper versions of the QLQ-C30 has been demonstrated elsewhere. This analysis provides additional evidence of the test-retest reliability of the IVR version of the QLQ-C30.

LEVERAGING PATIENT-REPORTED OUTCOMES TO DEFINE FATIGUE IN CANCER

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Patients and methods: We assessed 18% of cancer patients’ experience of fatigue due to cancer or its treatment. Only one claim for “cancer-related fatigue” (CF) has been granted by the US Regulatory Authorities. To date, the definition or diagnosis of CF remains a subject for debate within the clinical community. Although several self-report symptom assessment scales are available, the lack of an accepted conceptual framework articulating those concepts important to patients has hampered research in this field. Developing a preliminary conceptual framework able to underpin patients’ experience of CF is central to gathering meaningful data. Qualitative articles with verbatim patient quotes were reviewed and synthesized to begin a large effort to develop such a framework.

METHODS: A systematic search identified 95 articles published between 1996 and 2007 containing patient quotes. Search terms included fatigue, tiredness, asthenia, weakness, or asthenia. Two researchers independently reviewed articles; 645 quotes were extracted and systematically analyzed to identify concepts and language used to describe patients’ CF experiences. RESULTS: CF is more intense than pre-diagnosis or treatment tiredness. Terms such as “overwhelmed,” “unusual,” and “all-encompassing” were used to describe CF. Quotes referring to “tiredness” were often associated with adverbs (very, extremely) or patients’ idiomatic phrases intensifying “tiredness” (e.g. “dead-tired,” “sick-tired”) to distinguish tiredness due to CF. Metaphors depicted the severity and debility associated with CF. Conclusions: Findings suggest that extant CF assessments fail to capture the unique experience of CF as described by patients. Publication bias and lack of primary data from which quotes were drawn are study limitations. Rigorous qualitative research with patients with different types and stages of cancer is needed to concisely and comprehensively describe the experience of CF and its impact.

FACTORS IMPACTING THE HEALTH RELATED QUALITY OF LIFE IN FEMALE BREAST CANCER PATIENTS – AN OBSERVATIONAL, CROSS-SECTIONAL STUDY

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Objective: To estimate the impact of performance status (ECOG), age, comorbidities, perceptions of diagnosis, exposure to chemotherapy, and patients’ coping strategies on health related quality of life (HRQoL) in 800 adult female breast cancer patients in the USA and 5 European countries (France, Germany, Italy, Spain and UK). Methods: Data were drawn from the Adelphi Breast Cancer Disease Specific Programme (DBS), a cross-sectional study of consulting patients, undertaken in 2007. Physicians collected data on the next 7 patients presenting with breast cancer during the study period. Patients were asked to report on their HRQoL. FACT-B, OLS regressions were performed using STATA. Diagnostic tests were performed (joint significance, misclassification and multicollinearity) and White standard errors were applied. RESULTS: Eight hundred (Europe, 686; USA, 114) patient records were analysed. FACT-B scores were significantly impacted in line with worsening EOCOG performance status (Grade 1: -7.44, overall; -5.94, USA; -13.48, Europe; all p < 0.001: Grade 2: -14.92, overall; -13.45, USA; -19.39, Europe; all p < 0.001: Grade 3: -22.04, overall; -20.87, USA; -23.94, Europe; all p < 0.001: except USA, p < 0.05). No Grade 4 patients were present in the sample. FACT-B scores were lower overall and in Europe, in patients currently receiving chemotherapy (+9.13, overall; +9.78, Europe; all p < 0.001), those with a caregiver (+5.64, overall; +7.03, Europe; all p < 0.001). Longer diagnosis (>8.2, P < 0.05) and presence of mental health related comorbid conditions (~7.25, P < 0.05) were significant in US patients only. Age and heart related comorbid conditions were not significant. Models showed overall robustness to the diagnostic tests performed. CONCLUSIONS: A significant association between the patient-reported FACT-B scores and the physician-reported EOCOG performance status. The impact of the various factors identified, including chemotherapy use, mental health related comorbid conditions and time since diagnosis, can provide useful indicators to be taken into account in the management of breast cancer patients.

A METHODOLOGICAL APPROACH TO DEFINE A CLINICALLY RELEVANT CUTOFF POINT IN THE ORDINAL SCALE OF THE EORTC QLQ-C30 QUESTIONNAIRE


EORTC Brussels, Belgium; ULTRMl-Anderson Cancer Center, Houston, TX, USA; ‘City Hospital, Magdeburg, Magdeburg, Germany; University of British Columbia, Vancouver, BC, Canada; Medical University Graz, Graz, Austria; University of Sydney, Sydney, Australia; QOL Consulting, West Vancouver, BC, Canada; ‘York University Medical Center/Medical Center Haagden, Den Haag, Netherlands; ‘National Cancer Institute, Bethesda, MD, USA; ‘The Princess Margaret Hospital, Toronto, ON, Canada; ‘University of Regensburg, Regensburg, Germany; ‘University of Freiburg, Freiburg, Germany

OBJECTIVES: The objective of this analysis was to develop a new analytic methodology to identify a clinically relevant cut-off point in the EORTC QLQ-C30 ordinal pain scale score by comparing patient and clinician reporting for the same symptom. Ability to translate between clinician and patient reported symptoms will be useful in planned future analyses. METHODS: Closed European Organisation for Research and Treatment of Cancer Randomized Controlled Trials, where the pain symptom scale was scored at baseline by the patient (EORTC QLQ-C30) and the clinician [Common Toxicity Criteria (CTC)], were pooled and analysed to test the optimal cut-off point. The CTC was dichotomized as 0,1,2, 3, 4; defined as a clinically relevant cut-off point for clinical practice. Percent agreement with various dichotomizations of the QLQ-C30 pain scale was calculated, and McNemar’s test applied. Verification of the accuracy and generalizability of the findings was evaluated with a validation dataset, and by applying the same cut-off point on another symptom, i.e. fatigue. RESULTS: Data were available for pain (number of trials = 8, number of patients = 11214) and fatigue (n = 5, n = 1237). Model and validation set were obtained by splitting the dataset in half. Percent agreement and p values for McNemar tests, between patient and clinician dichotomized scores using different cut-off points for the QLQ-C30 scale, were: median <2.19 (x < 2.19, 66%, p < 0.01), quartile (≤> 3.0, 81%, p = 0.55), decade (≤> 4.0 vs. 4.0, 85%, p < 0.01). The quartile split reflects best the dichotomized CTC score. This was confirmed in the validation set (quartile cut-point: 82%, p = 0.86). However, when the quartile cut-off was applied to the QLQ-C30 fatigue scale, a significant difference (p < 0.01) between patient and clinician results was found. CONCLUSIONS: Our results indicate that a quartile split of the QLQ-C30 pain scale is optimal. However, a single cut-point may not generalise to other QLQ-C30 symptoms; symptom-specific cut-points may be required.