Breast cancer-specific HRQoL questionnaires

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| Breast Cancer Chemotherapy Questionnaire (BCQ) | Developed as an outcome measure in clinical trials of adjuvant chemotherapy | 30          | • Consequences of hair loss  
• Emotional dysfunction  
• Physical symptoms  
• Trouble/inconvenience  
• Fatigue  
• Nausea  
• Positive well-being | In 418 patients with Stage II cancer - correlations with SF-36 physical (0.58) and mental (0.60), Spitzer (0.62), Karnofsky (0.46). Discriminated patients grouped by treatment status; no such difference was identified by the SF-36 or Spitzer.  
In 164 patients with lymph-node positive breast cancer - predicted early treatment discontinuation even after accounting for age and chemotherapy-related side effects | In 418 patients with Stage II cancer - correlations with SF-36 physical (0.58) and mental (0.60), Spitzer (0.62), Karnofsky (0.46). Discriminated patients grouped by treatment status; no such difference was identified by the SF-36 or Spitzer.  
In 164 patients with lymph-node positive breast cancer - predicted early treatment discontinuation even after accounting for age and chemotherapy-related side effects | Mean change score in stable patients = -0.183 (n=184) |           |
| EORTCQLQ-BR23                        | Designed to supplement the EORTC core measure, the QLQ-C30.                  | 23          | • therapy side effects  
• arm symptoms  
• breast symptoms  
• body image  
• sexual functioning  
• sexual enjoyment  
• upset by hair loss  
• future perspective | In 496 Dutch, Spanish and US patients with Stages I-IV - discriminated patients grouped by disease stage, previous surgery, performance status, and treatment modality; responsive to performance status and treatment-induced change | In 496 Dutch, Spanish and US patients with Stages I-IV - discriminated patients grouped by disease stage, previous surgery, performance status, and treatment modality; responsive to performance status and treatment-induced change | 0.46-0.94 |               |
| FACT-B                               | Includes the FACT core measure, the FACT-G.                                  | 37          | FACT-G -  
• physical wellbeing (PWB)  
• emotional wellbeing (EWB)  
• social/family wellbeing (SWB)  
• functional wellbeing (FWB)  
Breast cancer subscale (BCS)  
• symptoms  
• body image  
• bothered by hair loss | In 295 patients with Stages I-IV breast cancer - All subscales and FACT-G, FACT-B and TOI discriminated patients grouped by patient-rated performance status and were associated with POMS scores; all scores except SWB and EWB discriminated patients grouped by clinician-rated performance status; and PWB, EWB, FWB, FACT-G, FACT-B and TOI discriminated patients grouped by extent of disease.  
In 47 patients with advanced breast cancer - PWB, FWB, FACT-B, BCS and TOI were responsive to change in performance status; these subscales and EWB and FACT-G were also responsive to changes in FLIC scores. | In 295 patients with Stages I-IV breast cancer - All subscales and FACT-G, FACT-B and TOI discriminated patients grouped by patient-rated performance status and were associated with POMS scores; all scores except SWB and EWB discriminated patients grouped by clinician-rated performance status; and PWB, EWB, FWB, FACT-G, FACT-B and TOI discriminated patients grouped by extent of disease.  
In 47 patients with advanced breast cancer - PWB, FWB, FACT-B, BCS and TOI were responsive to change in performance status; these subscales and EWB and FACT-G were also responsive to changes in FLIC scores. | 0.63-0.86 | 0.85-0.89 |
FACT-B cont.

- worry about effect of stress on illness
- worry about members of family also getting breast cancer
- bothered by weight change

**Scoring**

FACT-B = FACT-G + BCS

Trials Outcome Index (TOI) = PWB + FWB + BCS

In 306 patients with primary or advanced breast cancer on hormone therapy – PWB, SWB, FACT-B and BCS discriminated between patients grouped by treatment (tamoxifen vs anastrozole vs megestrol acetate vs adjuvant tamoxifen vs chemo ablation vs no endocrine treatment); groups were variously discriminated by individual symptoms of an additional 18 item \(^{15}\) endocrine symptom subscale (FACT-ES); FACT-G, FACT-B, BCS and TOI scores discriminated patients who were disease free and those with advanced disease; the ES subscale was responsive to increase in symptoms of patients during endocrine therapy and reductions in patients on HRT.

In 297 patients undergoing sentinel node guided axillary therapy and 29 patients attending a lymphoedema clinic \(^{14}\) - SWB, BCS, FACT-B scores and an additional 4-item scale for assessing arm symptoms discriminated pre-operative vs lymphoedema clinic patients; arm symptoms, FACT-G, FACT-B, FACT-B+4 and TOI scores were responsive to change from pre- to 4 weeks post-surgery; arm symptoms and TOI were also responsive to differences 4 weeks to 12 weeks post-surgery.

A minimal clinically important difference (MCID) has been defined as 7-8 points on total FACT-B score, 2-3 points on the BCS, and 5-6 points on the TOI \(^{15}\)

Analysis using item response theory suggested adequate cultural equivalence in item functioning between US and Austrian samples. \(^{16}\)
| International Breast Cancer Study Group - Quality of Life Core Form (IBCSG-QLC) | Developed as an outcome measure for adjuvant trials | 10 | • physical well-being  
• mood  
• perceived social support  
• coping  
• subjective health estimation  
• side-effects (tiredness, appetite, nausea / vomiting, hot flushes, restrictions in arm movement) | The IBSG-QLC has not been validated as a whole. However, each item was selected on the basis of association with performance status, tumour response, survival time and various validated measures in previous research (e.g. 17-19). See 20 for a summary. |

| Quality of Life Instrument - Breast Cancer Patient Version | A version of the City of Hope QOL Cancer Survivor questionnaire that includes issues of concern specific to breast cancer, including fear of recurrence, fertility issues, and concern over breast cancer in female relatives | 46 | • Physical wellbeing  
• Psychological wellbeing  
• Social concerns  
• Spiritual wellbeing | Explored via qualitative interviews with 21 survivors.21 |

* While standards vary, Cronbach’s alphas of between 0.70 and 0.90 are widely accepted as an indication of satisfactory internal consistency.
# An intraclass correlation coefficient (ICC) > 0.70 is typically considered an indication of satisfactory test-retest reliability.
$ All validation data refers to a 9 item breast cancer subscale; the version currently available on the FACIT website has 10 items.
** Validation data refers to an 18-item endocrine symptom subscale; the FACT-ES available on the FACIT website has 19 items listed under additional concerns.
References

1. Levine M, Guyatt G, Gent M, et al. Quality of life in stage II breast cancer: an instrument for clinical trials. *J Clin Oncol.* 1988;6(12):1798-1810 A questionnaire has been developed for use as an outcome measure in clinical trials of adjuvant chemotherapy in women with stage II breast cancer. The selection of items for this Breast Cancer Chemotherapy Questionnaire (BCQ) was based on the problems and experiences felt to be most important by women undergoing adjuvant chemotherapy. The BCQ consists of 30 questions that focus on loss of attractiveness, fatigue, physical symptoms, inconvenience, emotional distress, and feelings of hope and support from others. The BCQ, other instruments that evaluate quality-of-life (Spitzer, Karnofsky, and Rand), and patient and physician global assessments were administered serially to 418 patients taking part in a randomized trial comparing a 12-week regimen and a 36-week regimen of adjuvant chemotherapy. The validity of the BCQ is supported by its correlation with the Rand Emotional (r = .58), Rand Physical (r = .60), and Spitzer (r = .62) questionnaires. The BCQ correlated more strongly with global ratings of both physical and emotional function by the patients and their physicians than the other instruments. A comparison of the quality-of-life outcomes of patients in the two treatment groups in the period beyond 3 months after initiation of treatment, when one group had completed the treatment course and the other was still on treatment, revealed that the BCQ and Karnofsky were the only instruments able to demonstrate differences between the groups (P less than .0001). Hence, the BCQ is a valid and responsive method of assessing treatment-related morbidity in patients receiving adjuvant chemotherapy for stage II breast cancer.

2. Guyatt GH, Deyo RA, Charlson M, Levine MN, Mitchell A. Responsiveness and validity in health status measurement: a clarification. *Journal of Clinical Epidemiology.* 1989;42(5):403-408 We present data from two studies which clarify the relationship between the responsiveness and validity of instruments designed to measure health status in clinical trials. In a controlled trial of long vs short duration adjuvant chemotherapy for women with Stage II breast cancer, the Breast Cancer Chemotherapy Questionnaire (BCQ) proved valid as a measure of subjective health status and was able to distinguish long vs short arms. Well validated measures of physical and emotional function developed by the Rand Corporation were unable to distinguish between the two groups. The Eastern Co-operative Oncology Group Criteria (ECOG) distinguished the two groups, but failed criteria of clinical sensibility as a measure of subjective health status. In a study of patients with Crohn's disease and ulcerative colitis, the Inflammatory Bowel Disease Questionnaire (IBDQ) showed small intrasubject variability over time. Gobal ratings of change showed moderate to high correlations with changes in IBDQ score, and patients who reported overall improvement or deterioration showed large changes in IBDQ score. Each of these findings support, in different ways, the reproducibility, validity, and responsiveness of the questionnaire. While the same data can at times bear on both validity and responsiveness, when assessing evaluative instruments it is useful to make a conceptual distinction between the two.

3. Whelan TJ, Levine M, Julian J, Kirkbride P, Skingley P. The effects of radiation therapy on quality of life of women with breast carcinoma: results of a randomized trial. Ontario Clinical Oncology Group. *Cancer.* May 15 2000;88(10):2260-2266 BACKGROUND: The purpose of this study was to evaluate the effect of breast irradiation on quality of life, including cosmetic outcome, for patients enrolled in a clinical trial. METHODS: Between 1984 and 1989, a randomized trial was conducted in Ontario, Canada, in which women with lymph node negative breast carcinoma who had undergone lumpectomy and axillary lymph node dissection were randomized to either breast irradiation or no further treatment. A modified version of the Breast Cancer Chemotherapy Questionnaire (BCQ) was administered to women at baseline, 1 month (4 weeks), and 2 months (8 weeks) after randomization. Irritation of the skin of the breast, breast pain, and appearance of the breast to the patient were also assessed every 3 months for the first 2 years of the study. RESULTS: Of 837 patients, 416 were randomly allocated to radiation therapy and 421 to no further treatment. The mean change in quality of life from baseline to 2 months was -0.05 for the radiation group and +0.30 for the control group. The difference between groups was statistically significant (P = 0.0001). Longer term radiation therapy increased the proportion of patients who were troubled by irritation of the skin of the breast and breast pain. Radiation therapy did not increase the proportion of patients at
2 years who were troubled by the appearance of the treated breast; 4.8% in irradiated and nonirradiated patients (P = 0.62). CONCLUSIONS: Breast irradiation therapy had an effect on quality of life during treatment. After treatment, irradiated patients reported increased breast symptoms compared with controls. However, no difference was detected between groups at 2 years in the rates of skin irritation, breast pain, and being upset by the appearance of the breast.


5. Richardson LC, Wang W, Hartzema AG, Wagner S. The Role of Health-Related Quality of Life in Early Discontinuation of Chemotherapy for Breast Cancer. Breast Journal. 2007;13(6):581-587 To examine the role of health-related quality of life (HRQOL) in early treatment discontinuation among women enrolled in a breast cancer clinical trial. A total of 464 women were enrolled in the Eastern Cooperative Oncology Group randomized controlled trial of adjuvant regimens comparing six cycles of cytoxan, adriamycin and 5-flurouricil (5-FU) with a 16-week regimen (weekly therapy with cytoxan, adriamycin, vincristine, methotrexate, and 5-FU) among women with lymph node positive breast cancer. One hundred sixty-four women participated in the HrQL substudy using the Breast Chemotherapy Questionnaire, which was designed to measure HRQOL in women receiving chemotherapy. Changes in global HRQOL score were examined over time as a predictor of early treatment discontinuation using generalized estimation equations (GEE) modeling and Cox proportional hazards regression. We considered early treatment discontinuation as a longitudinal binary variable determined at each time point HRQOL was measured. The results of multivariate GEE model fitting indicated that declines in HRQOL (p = 0.04), older age (p = 0.02), higher degree of nausea (p = 0.02), higher degree of neurosensory toxicity (0.03) and lower degrees of hair loss (p = 0.004) were correlated with early treatment discontinuation. We then fitted a proportional hazard regression model for time to early discontinuation with HRQOL score as a time-dependent covariate. The results were identical. Declines in HRQOL during therapy predicted early treatment discontinuation even after accounting for age and chemotherapy-related side effects. In the age of ever more aggressive treatments for breast cancer, women's perception of the impact of these treatments on their lives will become more important.

6. Sprangers MA, Groenvold M, Arraras JI, et al. The European Organization for Research and Treatment of Cancer breast cancer-specific quality-of-life questionnaire module: first results from a three-country field study. Journal of Clinical Oncology. Oct 1996;14(10):2756-2768 PURPOSE: To construct a breast cancer-specific quality-of-life questionnaire (QLQ) module to be used in conjunction with the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and to test its reliability and validity cross-culturally. PATIENTS AND METHODS: Module construction took place after the EORTC guidelines for module development. The module--the QLQ-BR23--consists of 23 items covering symptoms and side effects related to different treatment modalities, body image, sexuality, and future perspective. This module was tested in 170 Dutch, 168 Spanish, and 158 American cancer patients at two points in time. The timing for the Dutch and Spanish patients was before and during treatment with radiotherapy or chemotherapy. For the American patients, the questionnaire was administered at admission at the breast clinic and 3 months after the first assessment. RESULTS: Multitrait scaling analysis confirmed the hypothesized structure of four of the five scales. Cronbach's alpha coefficients were, in general, lowest in Spain (range; .46 to .94) and highest in the United States (range; .70 to .91). On the basis of known-groups comparisons, selective scales distinguished clearly between patients differing in disease stage, previous surgery, performance status, and treatment modality, according to expectation. Additionally, selective scales detected change over time as a function of changes in performance status and treatment-induced change. CONCLUSION: These results lend support to the clinical and cross-cultural validity of the QLQ-BR23 as a supplementary questionnaire for assessing specific quality-of-life issues relevant to patients with breast cancer.

by the Monash Interview for Liaison Psychiatry; quality-of-life data based on the the European Organization for Research and Treatment of Cancer quality-of-life questionnaire (QLQ)-C30 (core) and QLQ-BR23 (breast module) instruments. RESULTS: 45% of the women (135/303) had a psychiatric disorder; 42% (127) of the sample had depression or anxiety, or both; there was minor depression in 82 (27.1%), an anxiety disorder in 26 (8.6%), major depression in 29 (9.6%) and a phobic disorder in 21 (6.9%). 20% of women (61) had more than one disorder. On quality-of-life measures nearly one-third of the women felt less attractive and most had lost interest in sexual activity. There was substantial distress about hair loss. Symptoms of lymphoedema were described by 13 women (4.3%). Breast conservation surgery was associated with a better body image (P<0.01). CONCLUSION: Women recently diagnosed with early-stage breast cancer have high rates of psychiatric and psychological disturbance. Quality of life is substantially affected. Clinicians should actively explore their patients' psychological adjustment to enable early recognition and treatment of these disorders.

8. Arving C, Sjoden P-O, Bergh J, et al. Individual psychosocial support for breast cancer patients: a randomized study of nurse versus psychologist interventions and standard care. Cancer Nursing. May-Jun 2007;30(3):E10-19 In a prospective, randomized study, an individual psychosocial support intervention performed by specially trained oncology nurses, or psychologists, were compared with standard care. Consecutive primary breast cancer patients about to start adjuvant therapy (n = 179) were included. Data were supplied by the questionnaires European Organisation for Research and Treatment of Cancer Quality of Life Study Group Core Quality of life questionnaire with 30 questions (EORTC QLQ-C30) and Breast Cancer Module with 23 questions (BR23), the Hospital Anxiety and Depression Scale, Spielberger’s State-Trait Anxiety Inventory, and the Impact of Event Scale before randomization and 1, 3, and 6 months later. Patient files provided data on utilization of psychosocial support offered in routine care. Global quality of life/health status, nausea and vomiting, and systemic therapy side effects were the subscales showing significant Group by Time interactions, favoring the interventions. Intervention groups improved statistically significantly more than the standard care group regarding insomnia, dyspnea, and financial difficulties. Nurse patients experienced less intrusion compared with the standard care group. All groups showed statistically and clinically significant improvements with time on several subscales. The intervention groups, however, improved to a greater extent. Fewer patients in the intervention groups used psychosocial hospital support compared with the standard care group. In conclusion, psychosocial support by specially trained nurses using techniques derived from cognitive behavioral therapy is beneficial for breast cancer patients and may be a realistic alternative in routine cancer care.

9. Chuojo M, Mikami I, Takashima S, et al. A feasibility study of psychosocial group intervention for breast cancer patients with first recurrence. Supportive Care in Cancer. Jul 2005;13(7):503-514 GOALS OF WORK: The effects of psychosocial group interventions on improving quality of life (QOL) for patients with recurrent breast cancer are not well known. The objective of this study was to assess the feasibility of a psychosocial group intervention in Japanese women with first recurrence of breast cancer. PATIENTS AND METHOD: The subjects were consecutively selected from among patients who were diagnosed with a first recurrence of breast cancer. We conducted a 6-week psychosocial group intervention. QOL was assessed using the Profile of Mood States (POMS), the Impact of Event Scale-Revised, the Mental Adjustment to Cancer (MAC) scale, and the European Organization for Research and the Treatment of Cancer (EORTC) Quality of Life Questionnaire-Cancer 30/Breast module 23 (QLQ-C30/Br23) at baseline then immediately and 3 and 6 months after completion of the intervention. RESULTS: Among 58 eligible patients, written consent was obtained from 28 (48%), and the final evaluation was conducted on 19 subjects. The repeated measured analysis of variance (ANOVA) revealed a significant change in tension-anxiety, depression-dejection, anger-hostility and total mood disturbance on the POMS, helplessness/hopelessness on the MAC scale, and body image and future perspective on the QLQ-C30/Br23. Dunnett’s test revealed a significant difference in these scores between baseline and 3 months after the intervention but no difference between baseline and 6 months after the intervention. CONCLUSION: These results suggested the possibility of a short-term effectiveness of the intervention; however the results were inconclusive because of selected small samples.


BACKGROUND: Sentinel lymph node biopsy in women with operable breast cancer is routinely used in some countries for staging the axilla despite limited data from randomized trials on morbidity and mortality outcomes. We conducted a multicenter randomized trial to compare quality-of-life outcomes between patients with clinically node-negative invasive breast cancer who received sentinel lymph node biopsy and patients who received standard axillary treatment. METHODS: The primary outcome measures were arm and shoulder morbidity and quality of life. From November 1999 to October 2003, 1031 patients were randomly assigned to undergo sentinel lymph node biopsy (n = 515) or standard axillary surgery (n = 516). Patients with sentinel lymph node metastases proceeded to delayed axillary clearance or received axillary radiotherapy (depending on the protocol at the treating institution). Intention-to-treat analyses of data at 1, 3, 6, and 12 months after surgery are presented. All statistical tests were two-sided. RESULTS: The relative risks of any lymphedema and sensory loss for the sentinel lymph node biopsy group compared with the standard axillary treatment group at 12 months were 0.37 (95% confidence interval [CI] = 0.23 to 0.60; absolute rates: 5% versus 13%) and 0.37 (95% CI = 0.27 to 0.50; absolute rates: 11% versus 31%), respectively. Drain usage, length of hospital stay, and time to resumption of normal day-to-day activities after surgery were statistically significantly lower in the sentinel lymph node biopsy group (all P < .001), and axillary operative time was reduced (P = .055). Overall patient-recorded quality of life and arm functioning scores were statistically significantly better in the sentinel lymph node biopsy group throughout (all P ≤ .003). These benefits were seen with no increase in anxiety levels in the sentinel lymph node biopsy group (P > .05). CONCLUSION: Sentinel lymph node biopsy is associated with reduced arm morbidity and better quality of life than standard axillary treatment and should be the treatment of choice for patients who have early-stage breast cancer with clinically negative nodes.

PURPOSE: To determine the effects of breast cancer-specific print materials and step pedometers on physical activity (PA) and quality of life (QoL) in breast cancer survivors. PATIENTS AND METHODS: Breast cancer survivors (N = 377) were randomly assigned to receive one of the following: a standard public health recommendation for PA, previously developed breast cancer-specific PA print materials, a step pedometer, or a combination of breast cancer-specific print materials and step pedometers. The primary outcome was self-reported moderate/vigorous PA minutes per week. Secondary outcomes were QoL (Functional Assessment of Cancer Therapy-Breast), fatigue, self-reported brisk walking, and objective step counts. Assessments were conducted at baseline and postintervention (12 weeks). RESULTS: Attrition was 10.3% (39 of 377). On the basis of linear mixed-model analyses, PA increased by 30 minutes/week in the standard recommendation group compared with 70 minutes/week in the print material group (mean difference, 39 minutes/week; 95% CI = -10 to 89; d = 0.25; P = .117), 89 minutes/week in the pedometer group (mean difference, 59 minutes/week; 95% CI, 11 to 108; d = 0.38; P = .017), and 87 minutes/week in the combined group (mean difference, 57 minutes/week; 95% CI, 8 to 106; d = 0.37; P = .022). For brisk walking minutes/week, all three intervention groups reported significantly greater increases than the standard recommendation group. The combined group also reported significantly improved QoL (mean difference, 5.8; 95% CI, 2.0 to 9.6; d = 0.33; P = .003) and reduced fatigue (mean difference, 2.3; 95% CI, 0.0 to 4.7; d = 0.25; P = .052) compared with the standard recommendation group. CONCLUSION: Breast cancer-specific PA print materials and pedometers may be effective strategies for increasing PA and QoL in breast cancer survivors. A combined approach appears to be optimal. CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov Identifier NCT00221221.

GOALS: This study was designed to assess the effectiveness of progressive muscle relaxation training (PMRT) and guided imagery (GI) in reducing the anticipatory nausea and vomiting (ANV) and postchemotherapy nausea and vomiting (PNV) of patients with breast cancer and to measure their effects on the patients' quality of life (QoL). PATIENTS AND METHODS: Thirty chemotherapy-naive patients with breast cancer were randomized to the PMRT and GI group and 30 to the control group. Before each of six cycles of adjuvant chemotherapy, each patient was administered a self-report Multiple Affect Adjective Checklist (MAACL), and incidents of ANV and PNV for the first three postchemotherapy days were recorded. All patients were administered the Functional Assessment of Cancer Therapy-Breast (FACT-B) at baseline and after 3 and 6 months. RESULTS:
We found that the PMRT and GI group was significantly less anxious, depressive, and hostile than the control group. We also found that the PMRT and GI group experienced significantly less ANV and PNV and that 6 months after CT, the QoL of the PMRT and GI group was higher than that of the control group. CONCLUSION: These results indicate that PMRT and GI were associated with both the improvements in ANV and PNV and in the QoL of patients with breast cancer.

14. Coster S, Poole K, Fallowfield LJ. The validation of a quality of life scale to assess the impact of arm morbidity in breast cancer patients post-operatively. Breast Cancer Research & Treatment. Aug 2001;68(3):273-282 This paper documents the validation of a quality of life scale (QOL) designed to assess the impact of arm morbidity on patients following breast cancer surgery. A four item arm subscale was developed to supplement a multi-dimensional, validated breast cancer QOL tool, the functional assessment of cancer therapy (FACT-B). The new questionnaire, the FACT-B + 4, was validated on 279 women participating in a trial of sentinel node guided axillary therapy and 29 women attending a lymphoedema clinic. The subscale demonstrated good internal consistency (alpha co-efficient = 0.62 to 0.88) and stability (test-retest reliability = 0.97). Lymphoedema patients reported significantly greater arm problems than a matched sample of pre-operative trial participants. The lymphoedema group also scored lower than trial participants on the FACT-B + 4 indicating a poorer quality of life (p < 0.05). A subset of 66 trial patients who had completed three consecutive assessments was used to evaluate the sensitivity of the questionnaire to change over time. Scores on the FACT-B + 4 were found to decline significantly between the pre-operative assessment and post-operative assessment at 1 month. Arm problems significantly increased during this period. FACT-B + 4 score increased again from 1 month to 12 weeks post-surgery and symptoms reduced, as the extent of arm morbidity resolved. The FACT-B + 4 appears to be psychometrically robust and sensitive to patient rehabilitation, making it suitable for use in longitudinal surgical trials. Given the dearth of existing scales available to measure arm morbidity, we hope this new tool will prove useful to researchers.

15. Eton DT, Cella D, Yost KJ, et al. A combination of distribution- and anchor-based approaches determined minimally important differences (MIDs) for four endpoints in a breast cancer scale. Journal of Clinical Epidemiology. Sep 2004;57(9):898-910 OBJECTIVE: To determine distribution- and anchor-based minimal important difference (MID) estimates for four scores from the Functional Assessment of Cancer Therapy-Breast (FACT-B): the breast cancer subscale (BCS), Trial Outcome Index (TOI), FACT-G (the general version), and FACT-B. STUDY DESIGN AND SETTING: We used data from a Phase III clinical trial in metastatic breast cancer (ECOG study 1193; n=739) and a prospective observational study of pain in metastatic breast cancer (n=739) and a prospective observational study of pain in metastatic breast cancer (n=129). One third and one half of the standard deviation and 1 standard error of measurement were used as distribution-based criteria. Clinical indicators used to determine anchor-based differences included ECOG performance status, current pain, and response to treatment. RESULTS: FACT-B scores were responsive to performance status and pain anchors, but not to treatment response. By combining the results of distribution- and anchor-based methods, MID estimates were obtained: BCS=2-3 points, TOI=5-6 points, FACT-G=5-6 points, and FACT-B=7-8 points. CONCLUSION: Distribution- and anchor-based estimates of the MID do show convergence. These estimates can be used in combination with other measures of efficacy to determine meaningful benefit and provide a basis for sample size estimation in clinical trials.

16. Hahn EA, Holzner B, Kemmler G, Sperner-Unterweger B, Hudgens SA, Cella D. Cross-cultural evaluation of health status using item response theory: FACT-B comparisons between Austrian and U.S. patients with breast cancer. Evaluation & the Health Professions. Jun 2005;28(2):233-259 To make meaningful cross-cultural comparisons of health-related quality of life (HRQOL) or to pool international research data, it is essential to create culturally unbiased measures that detect clinically important differences between patients. We evaluated the measurement properties of the Functional Assessment of Cancer Therapy-Breast (FACT-B) in 111 Austrian and 144 U.S. patients with breast cancer using item response theory (IRT) methods. A small number of items were identified as displaying statistically significant differential item functioning (DIF), suggesting possible measurement bias. The majority of the items functioned similarly between the two cultural groups. U.S. patients reported lower (worse) physical function and well-being compared with Austrian patients, higher (better) social/family well-being and similar emotional well-being, before and after adjustment for DIF. IRT and related measurement models provide useful methods for assessing cross-cultural equivalence and determining which items can be pooled across languages before analyzing HRQOL data. Determination of clinically significant cross-cultural differences will require additional investigation.

Linear analogue self-assessment (LASA) scales were used to measure general well-being and specific factors (mood, pain, nausea and vomiting, appetite, breathlessness, physical activity) in patients receiving therapy for malignant melanoma, small cell bronchogenic carcinoma (SCBC) or ovarian cancer. Among the patients with SCBC and melanoma, high correlations were observed between LASA scores for general well-being, mood and appetite. There was a significant relationship between performance status and LASA scores for general well-being, pain and appetite. Among patients with ovarian cancer, there was a significant association between performance status and LASA scores for general well-being, pain and appetite. Objective response category was related to change in LASA scores for pain. Changes in LASA scores during treatment reflected increased morbidity during radiotherapy in patients also receiving chemotherapy for SCBC. The LASA technique provides a convenient method for the assessment of quality of life in patients receiving cancer therapy, and potentially allows comparison of patient perception of treatment-related morbidities.


In previous studies of the side effects patients identified as important in cancer chemotherapy we identified eight groups of symptoms. Linear analogue self assessment (LASA) scales for these 8 items form a new instrument (GLQ-8) for measuring aspects of quality of life. Patients completed both GLQ-8 and five previously validated LASA scales, together with a new single global quality of life scale (GLQ uniscale) and the visual analogue version of the Spitzer QL Index. This analysis includes 166 patients, with 47 1-hr test-retest and 29 24-hr test-retest pairs. The new scales showed high reliability, with retest correlation coefficients exceeding 0.8 for all items except GLQ uniscale, appetite and anxiety on 1-hour retest, and all except nausea and numbness on 24-hour retest. Correlations were in general higher for the GLQ-8 items than for the 5 older LASA items, while inter-item correlations were lower. Comparisons of the new scales with established instruments and comparisons of new scale scores between known groups supported the validity of the new scales. We conclude that the GLQ-8 and GLQ uniscale are convenient and reliable instruments measuring aspects of quality of life in patients receiving cancer chemotherapy.


Four measures of patient functioning and a mood adjective list currently used in trials of the International Breast Cancer Study Group (IBCSG), and an 8-item Linear Analogue Self Assessment (LASA) instrument measuring specific side effects of cancer and cancer treatment (GLQ-8), were cross-validated against three established measures of quality of life, mood and psychological adjustment to cancer, in a heterogeneous sample of cancer patients. Correlations between new and established measures were high, indicating good convergent and concurrent validity. Compliance on the longer mood measures was relatively poor. Despite the difficulty in developing direct and methodologically sound measures of quality of life, the regular inclusion of practical indicators of aspects of quality of life in clinical trials would allow improved assessment of the cost-benefit ratio of treatment to outcome in cancer patients.


**PURPOSE:** Currently, 1,721,700 women are living with breast cancer in the United States. As the number of survivors of breast cancer continues to rise, so must our knowledge about unique quality-of-life concerns. This article reports the results of a study on quality of life in women with breast cancer and validates the model of quality of life in this population. **DESCRIPTION OF STUDY:** To explore these concerns and to validate a breast cancer quality-of-life model, 21 survivors of breast cancer, across three age strata (younger than 40 years, 40 to 60 years, and older than 60 years), were interviewed and asked to complete quantitative surveys on pain and quality of life. **RESULTS:** Across all age groups, unique issues of survivorship include those related to physical, psychological, social, and spiritual well-being. In the domain of physical well-being, the areas of worst outcome were in menstrual changes and fertility, fatigue, and pain. In the domain of psychological well-being, predominant needs were in the areas of fear of the spread of cancer, distress from surgery, recurrence, fear of second cancer, impact on self-concept, and fear of future tests. The social well-being subscale identified the greatest disruption in the area of family distress. The spiritual well-being subscale
showed greatest disruption in the area of uncertainty, although other aspects of this domain were usually rated in a positive direction (e.g., importance of religious activities). CLINICAL IMPLICATIONS: The data demonstrated the need for further research, assessment, and intervention across each of the quality-of-life domains. There is a significant need to address physical problems; however, the psychological domain demonstrated the greatest area of distress. The multidimensional needs of breast cancer survivors emphasize the need for multidisciplinary collaboration. [References: 20].