An Updated Systematic Review of the EORTC QLQ Modules and the FACT-B for Assessing Quality of Life in Breast Cancer Patients

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Introduction

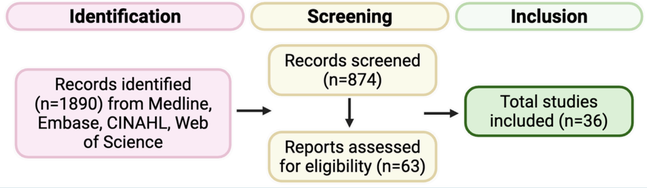
- Breast cancer is the most common cancer in women globally.
- Advancements in treatment generate the need for updated health-related quality of life (HRQoL) assessments on well-being and life satisfaction.
- Two prominent patient-reported outcome measures are the EORTC QLQ-BR23 and the FACT-B, first introduced in 1996 and 1997 respectively.
- A systematic review by Nguyen et al (2015) found the EORTC modules to focus on physical function, while the FACT-B focused on emotional well-being.
- A comprehensive comparison between the updated EORTC QLQ-BR42 and -BR45 released in 2024, and the FACT-B (+4) remains necessary.

Aim

- To compare the content, psychometric performance, and clinical utility of the new EORTC QLQ breast modules (BR42, BR45) and the FACT-B (including FACT-B + 4) in assessing QoL in breast cancer patients.

Methods

- Studies from 2013 - May 2024 addressing development, validity, reliability, responsiveness, or global use of the questionnaires were included
- Screening/data extraction were completed by two independent reviewers with conflicts resolved by a third



Results

- **Development**: The EORTC QLQ-BR23 was updated to BR45 (2020) and then BR42 (2024) through 4 phases of trials to reflect emerging treatment side effects. The FACT-B has not been updated since the early 2000s but supplements new drug evaluations via agent-specific subscales.
- **Content**: EORTC QLQ-BR42 emphasizes physical/symptom-specific domains (e.g., body image, systemic side effects), while FACT-B focuses more on emotional, social, and functional well-being.
- **Translations**: The EORTC QLQ-BR42 and FACT-B have been translated to 80 and 61 languages respectively.
- **Validity & Reliability**: All tools demonstrated robust cross-cultural validity and internal consistency (Cronbach's α > 0.70 in most domains). BR45 and FACT-B + 4 validated in multiple languages and settings (BR23: Ethiopia, Morocco, Bahrain, Singapore, BR45: Ethiopia, Tanzania; FACT-B: US, Iran, Lebanon, Malaysia; FACT-B+4: Brazil, Spain, Saudi Arabia).
- **Responsiveness**: FACT-B demonstrated moderate responsiveness in several studies. No BR45 or BR42 responsiveness data published yet.

Table 1. Comparison of EORTC and FACT-B QoL measurements for breast cancer patients.

	EORTC QLQ-BR42	FACT-B
# of items (general + breast-specific)	30 + 42 = 72	27+10=37
Subscales	Systemic Symptoms Body Image Sexuality Arm-related symptoms Breast-related symptoms Target Symptoms Satisfaction	Physical well-being Social/family well-being Emotional well-being Functional well-being Breast cancer-specific subscale
Response options	Likert Scale (1-4)	Likert Scale (0-4)
Item format	Questions	Statements
Recall period	Past 1 week and 4 weeks	Past 1 week
Scoring	Patient scores are converted to a 0-100 scale. Higher functional & satisfaction scores indicate greater functioning & satisfaction. Higher systemic & target symptom scores indicate worse symptom levels.	The total score is the addition of each items' individual score. A higher total score implies a better QoL.

Conclusions

- The development and uptake of QoL tools are essential in the evaluation of newly developed breast cancer treatments
- Both EORTC and FACT-B instruments are valid, reliable, and responsive tools for assessing QoL in breast cancer patients.
- The EORTC modules provide greater depth in symptom-specific data which may make it more suitable for trials with targeted interventions.
- The Fact-B is more concise and may be better suited for broader QoL assessments focused on emotional/social evaluation.
- Both tools support global use with extensive translations and cultural validations.
- Selection between the two should be guided by study goals and patient population.
- Further validation of the new EORTC QLQ-BR42 questionnaire and longitudinal comparisons with FACT-B are warranted.

References

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Conflicts of Interest

Dr. Andrew Bottomley was a former employee of the EORTC, a former developer of the EORTC QoL tools, and has received salary and other payments from the EORTC. Dr. Daid Cella is the president of the FACIT.org. There are no conflicts of interest for the remaining authors.