RESEARCH ARTICLE

Health-related Quality of Life in Women with Breast Cancer: a Literature-based Review of Psychometric Properties of Breast Cancer-specific Measures

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Abstract

<u>Background</u>: Breast cancer is one of the most common cancers in women in the world. Health-related quality of life (HRQL) at treatment endpoint in cancer clinical trials is widely considered to be increasingly important. The aim of this review was to provide a literature-based assessment of the validity, reliability and responsiveness of breast cancer-specific HRQL instruments in women breast cancer patients. <u>Materials and Methods</u>: The databases consulted were Medline, PubMed, and Embase. The inclusion criteria required studies to: (1) involve use of HRQL measures; (2) cover women with breast cancer under standard treatment (surgery, radiation therapy, chemotherapy, hormone therapy, and targeted therapy); (3) involve the validity, reliability, or responsiveness of HRQL; (4) deal with validation of breast cancer-specific HRQL instruments. <u>Results</u>: A total of 16 studies were identified through the literature search that met the 4 inclusion criteria. Some seven instruments were assessed among these 16 studies: EORTC QLQ-BR23, FACT-B, FACT-ES, HFRDIS, LSQ-32, QLICP-BR, and SLDS-BC. EORTC QLQ-BR23, FACT-B, LSQ-32, QLICP-BR, and SLDS-BC are more general breast cancer-specific HRQL instruments. FACT-EB is the endocrine subscale combined with FACT-B in order to measure the side effects and putative benefits of hormonal treatment administered in breast cancer patients. HFRDIS is the HRQL measure focusing on hot flash concerns. <u>Conclusions</u>: This paper provides an overall understanding on the currently available breast cancer-specific HRQL instruments in women breast cancer patients.

Keywords: Breast cancer - health-related quality of life - instrument - validity - reliability

Introduction

Health-related quality of life (HRQL) at treatment endpoint in cancer clinical trials is now considered to be more and more important. HRQL data not only are intended to help clinical decision making on optimal treatment, but also provide inferential information about the experience (i.e., psychological and physical) of patients and can potentially aid prognosis (Montazeri et al., 1996; Goodwin et al., 2003; Montazeri, 2008; Munoz, 2010). Breast cancer is one of the most common cancers in women in both developed and developing countries. It was reported that there were about 1.38 million people diagnosed with breast cancer and ~458,000 deaths result from breast cancer each year. Furthermore, breast cancer is the most common cancer in women over the age of 20, which represents 26% of all cancer cases in women and 14% of all female cancer deaths. In recent years, the development in diagnostic screening and anticancer treatment has helped breast cancer patients survive/live longer, for whom treatment-related problems can have a major impact on their HRQL. Therefore, there has been a lot of interest in conducting HRQL studies among women with breast cancer (Goodwin et al., 2003; Montazeri, 2008; Lemieux et al., 2011).

There are a lot of issues concerning the quality of life for breast cancer patients. These include not only factors such as pain, fear of recurrence, fatigue, and impact on the family, which are common to a wide range of cancer diagnoses, but also the breast cancer-specific factors such as an hot flashes, an altered sense of femininity, feelings of decreased attractiveness, and problems with treatment-related arm swelling (Brady et al., 1997). Moreover, the adjuvant therapy for breast cancer patients cause other adverse effects. For example, adjuvant chemotherapy can cause nausea, vomiting, fatigue, alopecia, and sequelae, such as premature menopause and arthritic complaints; adjuvant hormonal therapy are accompanied by a number of toxicities related to estrogen withdrawal or antagonism, such as vasomotor symptoms, urogenital, and sexual dysfunction (Ganz et al., 2002; Goodwin et al., 2003; Whelan et al., 2005; Whelan; Pritchard, 2006).

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The purpose of this review is to provide a literature-based review on the assessment of the validity, reliability and responsiveness of breast cancer-specific HRQL instruments in women breast cancer patients and therefore, the overall appraisal of the currently available breast cancer-specific instruments that may inform clinicians and academic researchers in choosing the proper instrument for their patients.

Materials and Methods

Literature search was carried out using the following databases: Medline, PubMed, and Embase. A search strategy was adopted using the following key words 'quality of life', 'health related quality of life', 'breast cancer', 'measures', 'instruments', 'validity', 'reliability', 'survey', and 'questionnaire'. Key terms were applied in different combinations using "AND" and "OR" terms while querying the databases. Only manuscripts written in English were included. The date range of search was between 1980 and 2013.

Two reviewers were involved in identifying papers by screening the titles and abstracts of the included publications. For the appraisals on the psychometric properties of the instruments, the following inclusion criteria were applied in order to check for evidence: (1) the study involved using HRQL measure; (2) the study population was women with breast cancer under the standard treatments (surgery, radiation therapy, chemotherapy, hormone therapy, and targeted therapy). The study population was limited to adult women. Females less than 18 years of age were excluded from the review; (3) the study involved the validity, reliability, or responsiveness of HRQL; (4) Studies should deal with the validation of breast cancer-specific HRQL instrument. Studies that could not meet the above criteria were excluded in the review. Disagreement between the two reviewers was resolved by co-reviewing the full text of the article and consulting with another author.

All publications included in the review met the above predefined criteria that are considered important in the assessment of breast cancer-specific HRQL instrument validation. Table 1 summarizes the assessment of breast cancer-specific HRQL measures based on the paper by Terwee et al. (Terwee et al., 2007) and Scholtes et al. (Scholtes et al., 2011), which described the quality criteria for measurement properties of health status questionnaires. These criteria included content validity, criterion validity, construct validity, internal consistency, test-retest, responsiveness, floor and ceiling effects, and interpretability. If a breast cancer-specific HRQL measure met the quality criteria, it was marked as positive (+); on the contrary, if a measure did not meet the quality criteria, it was marked as negative (-); and if a measure met only part of the quality criteria, it was marked as positive-negative (±).

Results

This review intends to provide an overall understanding on the currently available breast cancer-specific

instruments. Seven breast cancer-specific instruments were reviewed among sixteen studies. EORTC QLQ-BR23, FACT-B, FACT-ES, HFRDIS, and SLDS-BC were developed in English, in which EORTC QLQ-BR23 and FACT-B have been translated into many different language versions. LSQ-32 and QLICP-BR were developed in Sweden and China, respectively. In the study of QLICP-BR, the authors also considered the influence of Chinese culture in the instrument; therefore, it may not be applicable to non-Chinese speaking countries.

EORTC QLQ-BR23, FACT-B, LSQ-32, QLICP-BR, and SLDS-BC are more general breast cancer-specific HRQL instruments; however, because of the variety of different treatment for and symptoms of breast cancer patients, general breast cancer-specific HRQL instruments may not capture the HRQL issues of some special treatment or symptoms (e.g. hot flashes or menopausal symptoms during the hormonal therapy for breast cancer patients). FACT-EB is the endocrine subscale combined with FACT-B to measure the side effects and putative benefits of hormonal treatment administered in breast cancer patients. Therefore, it can be a comprehensive instrument to measure the breast cancer patients with hormonal therapy. HFRDIS is the HRQL measures focusing on hot flash concerns. In the study of Carpenter J.S. (Carpenter, 2001), increasing hot flash frequency was associated with higher HFRDIS scores over time, however, women with improvement of hot flashes over time did not exhibit significantly less interference compared to women whose level of hot flashes remained stable. Therefore, the future study of HRFDIS may focus on the development of scales sensitive to both positive and negative changes in hot flashes.

Content validity was assessed in all seven instruments, mostly through patients' interview, literature review, and consultation with expert panel in field. Criterion validity was lacking in the studies of EORTC QLQ-BR23, FACT-ES, and HFRDIS; the study of FACT-B mentioned using 47 samples to assess concurrent validity, however, there was no explanation of how the concurrent validity was assessed. The studies of EORTC QLQ-BR23, FACT-B, FACT-ES, HFRDIS, and SLD-BC used the known group and/or convergent validity to support the construct validity; the principal component factor analysis was used in the studies of LSQ-32, QLICP-BR, and SLD-BC to support the construct validity.

Both internal-consistency and test-rest were assessed in the instruments of EORTC QLQ-BR23, FACT-B, FACT-ES, QLICP-BR, and SLD-BC. Test-retest weren't assessed in HFRDIS and LSQ-32 instruments. Because changes of hot flashes are on a daily basis, it is reasonable that test-retest reliability was not assessed in HFRDIS as it was expected to be low given the unreliable nature of the phenomenon (Carpenter, 2001). All seven instruments gave moderate to high reliability.

Responsiveness to changes over time for women patients with breast cancer was lacking in the studies of LSQ-32 and SLD-BC instruments. In the study of QLICP-BR, authors mentioned that paired t-test and SRM were used and showed that three of five domains and the overall instrument exhibited statistically significant change before

and after treatment; however, there was no external criteria or anchor for determining that patients had changed. The studies of EORTC QLQ-BR23, FACT-B, FACT-ES, and HFRDIS reported their responsiveness to determine the changes in women breast cancer patients using either clinical knowledge, such as between-group difference over time (radiotherapy vs. chemotherapy) in the original study of EORTC QLQ-BR23, or external measures, such as hot flash diary in the study of HFRDIS.

Discussion

This review intends to provide an overall understanding on the currently available breast cancer-specific instruments. Seven breast cancer-specific instruments were reviewed among sixteen studies. EORTC QLQ-BR23, FACT-B, FACT-ES, HFRDIS, and SLDS-BC were developed in English, in which EORTC QLQ-BR23 and FACT-B have been translated into many different language versions. LSQ-32 and QLICP-BR were developed in Sweden and China, respectively. In the study of QLICP-BR, the authors also considered the influence of Chinese culture in the instrument; therefore, it may not be applicable to non-Chinese speaking countries.

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In conclusion, the instruments of breast cancer-specific HRQL: EORTC QLQ-BR23, FACT-B, FACT-ES, and HRDIS showed reasonable validity, reliability, and responsiveness, therefore have fairly good psychometric properties to assess HRQL in women with breast cancer. EORTC QLQ-BR23 and FACT-B are most widely used and can be applied in a general fashion to female breast cancer patients. FACT-ES and HFRDIS focus on the impact on HRQL of breast cancer patients who receive hormonal treatment and who have hot flashes respectively; hence, they have good applicability for these subgroups in breast cancer patients. Future study may be warranted to develop the instrument of HRQL based on different breast cancer treatments, such as surgery.

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