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Original article

Validation of the electronic version of the BREAST-Q in the army of women study

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ABSTRACT

Women undergoing surgery for primary breast cancer can choose between breast conserving therapy and mastectomy (with or without breast reconstruction). Patients often turn to outcomes data to help guide the decision-making process. The BREAST-Q is a validated breast surgery–specific patient-reported outcome measure that evaluates satisfaction, quality of life, and patient experience. It was originally developed for paper-and-pencil administration. However, the BREAST-Q has increasingly been administered electronically. Therefore, the aim of this study was to evaluate the psychometric properties of an electronic version of the BREAST-Q in a large online survey. Women with a history of breast cancer surgery recruited from the Love/AVON Army of Women program completed an electronic version of the BREAST-Q in addition to the Impact of Cancer Survey and PTSD Checklist. Traditional psychometric analyses were performed on the collected data. BREAST-Q data were collected from 6748 women (3497 Breast Conserving Therapy module, 1295 Mastectomy module, 1956 Breast Reconstruction module). Acceptability was supported by a high response rate (82%), low frequency of missing data (<5%), and maximum endorsement frequencies (<80%) in all but 17 items. Scale reliability was supported by high Cronbach's α coefficients ($\geq$0.78) and item-total correlations (range of means, 0.65–0.91). Validity was supported by interscale correlations, convergent and divergent hypotheses as well as clinical hypotheses. The electronically administered BREAST-Q yields highly reliable, clinically meaningful data for use in clinical outcomes research. The BREAST-Q can be used in the clinical setting, whether administered electronically or using paper-and-pencil, at the choice of the patient and surgeon.

1. Introduction

Breast cancer is the second most common cancer among women in the United States, with an estimated 246,660 new diagnoses projected in 2016 [1]. Owing to advances in the field of surgical oncology, breast cancer patients and survivors now have many surgical options, which emphasizes the importance of understanding the long-term quality of life (QOL) outcomes [2]. Women undergoing surgery for primary breast cancer are increasingly making their own surgical decisions, and are often choosing between breast conserving therapy and mastectomy with or without breast reconstruction [3]. Although recent studies suggest breast conserving therapy has a survival benefit [4], patients often turn to satisfaction and QOL outcomes data to help guide the decision-making process [5,6].

Patient-reported outcome measures (PROMs) are increasingly used in clinical research, education, and patient care. The field of PRO measurement is expanding, and the number of condition-specific scales continues to grow. As such, the COnsensus-based Standards for the selection of health Measurement INstruments initiative has suggested guidelines for the validation of PROMs [7]. Hospitals and clinics are incorporating PROMs into patient care and

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Abbreviations: AOW, Army of Women; MEF, maximum endorsement frequency; PCL-C, PTSD Checklist–Civilian version; PROM, patient-reported outcome measure; PTSD, posttraumatic stress disorder; QOL, quality of life; TRAM, transverse rectus abdominis muscle.

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are more frequently capturing them in electronic medical records. It is therefore critical that electronically administered PROMs are demonstrated to have comparable psychometric validity to the paper-and-pencil version [8].

The BREAST-Q is a validated breast surgery–specific PROM that assesses patient satisfaction, QOL, and patient experience within breast surgery–specific domains [9,10]. The BREAST-Q can provide meaningful data that can be used to support quality metrics and evidence-guided surgical practices in oncologic breast and plastic surgery [11]. It has been widely used by clinicians and researchers to help patients and surgeons better understand outcomes [9–12]. A recent literature review identified 49 publications that used the BREAST-Q as an outcome measure, including 22,457 patients who completed at least one scale of the BREAST-Q [12]. For example, the BREAST-Q was used to compare satisfaction with silicone and saline implant reconstruction after mastectomy; this analysis revealed that satisfaction with the breast was higher among those who received silicone implants [13]. Another study reported psychosocial and sexual well-being after nipple-sparing and skin-sparing mastectomies with reconstruction and found that nipple-sparing mastectomy was associated with higher QOL [14]. Other researchers used the BREAST-Q to evaluate the effect of a decision aid for different breast reconstruction options [15]. An increasing number of cancer hospitals have incorporated the BREAST-Q into clinical care. At these hospitals, physicians use the BREAST-Q in routine clinical practice to follow the progress of individual patients.

The BREAST-Q was originally developed and validated using a paper-and-pencil approach [9]. Given the uptake of the BREAST-Q in research and clinical practice, it is necessary to examine its psychometric performance when data are collected in an electronic format. The aim of this study was to examine the performance and clinical relevance of the BREAST-Q in an online community and to assess the psychometric validity of web-based completion.

2. Methods

2.1. Study design

A sample of participants were recruited from the Army of Women (AOW), an online community started in 2008 by the Dr. Susan Love Research Foundation with the goal of connecting breast cancer researchers to women with and without breast cancer [11]. The AOW Scientific Advisory Committee accepted this study, as previously described, with ethics approval obtained from the Duke University Medical Center Institutional Review Board and the Cancer Protocol Committee in June 2012 [16].

A recruitment e-mail (e-blast) was sent to AOW members, with a follow-up e-mail sent to eligible and interested participants. Women were invited to participate if they had undergone surgery for breast cancer and were able to complete the surveys in English. Participants completed a demographic survey and were directed to take either the BREAST-Q Breast Conserving Therapy, BREAST-Q Mastectomy, or BREAST-Q Breast Reconstruction postoperative module on the basis of their responses to demographic questions. Patients who completed the Breast Reconstruction module but had revision reconstruction surgery or had undergone surgery after recurrence were excluded from this validation study, as their experience was complex and could confound results. In addition to the BREAST-Q, participants also completed the Impact of Cancer Version 2 [17,18] and the PTSD Checklist-Civilian version (PCL-C) [19,20]. These two breast cancer–specific PROMs were used to establish construct validity via comparisons with the BREAST-Q scales.

2.2. Measures

2.2.1. BREAST-Q

The BREAST-Q was designed to assess the unique outcomes of breast surgery patients. The originally described core domains, which were identified through patient interviews, were physical well-being, psychosocial well-being, sexual well-being, satisfaction with breast, satisfaction with outcome, and satisfaction with care. Modules specific to different types of breast surgery were developed, with scales measuring different domain constructs. For example, the Breast Reconstruction module contains a different satisfaction with breast scale than the Breast Conserving Therapy module. Items for each scale are evaluated with multiple response options. Raw scores are added and converted to a score from 0 (worse) to 100 (best). In the original BREAST-Q development study and subsequent psychometric validation study, BREAST-Q data were collected via postal surveys sent to breast surgery patients [9,21]. The BREAST-Q was developed using Rasch measurement theory analysis. Paper-based assessments have demonstrated high internal consistency, with a Cronbach's α of 0.81–0.97, and test-retest reproducibility, as measured by intraclass correlation coefficients of 0.73–0.96, for each scale within the modules [9].

2.2.2. Impact of Cancer Version 2

The Impact of Cancer Version 2 is a 47-item questionnaire intended to assess the effect that cancer has had on the health-related QOL of long-term survivors [17,18]. The questionnaire consists of two higher-order scales, the positive impact summary scale and the negative impact summary scale, each with four scales. The negative impact summary has the following scales: appearance concerns, body change concerns, life interference, and worry. For each item, respondents indicate his or her agreement with five response options that range from “strongly disagree” to “strongly agree.” The scale scores represent the mean of the item responses within the scale. High scores represent a higher impact; high negative impact scores are worse than low negative impact scores. The negative impact and positive impact summary score is a mean of the scale scores. The Impact of Cancer Version 2 has demonstrated high internal consistency (Cronbach's α statistics, 0.76–0.89) when distributed by mail to survivors of early-stage breast cancer [18].

2.2.3. PCL-C

The PCL-C is a self-administered checklist of key symptoms of posttraumatic stress disorder (PTSD) in the civilian population and consists of 17 items that correspond to the Diagnostic and Statistical Manual of Mental Disorders 4th ed. [19]. The items address four distinct characteristics of PTSD: re-experiencing, avoidance, numbing, and hyperarousal. Respondents indicate how bothered by a symptom they have been during the past month using a 5-point scale, ranging from “not at all” (1 point) to “extremely” (5 points). Items are summed to produce a total PTSD severity score. The instrument has been used previously to assess symptoms of PTSD in breast cancer survivors [22,23]. The PCL-C has shown high internal consistency among domestic violence victims [24], college students who have experienced trauma [20], and bone marrow transplant patients [25] when completed in person, by mail, and by telephone interview. The Cronbach's α for the total score in these populations ranged from 0.89 to 0.94 [20,24,25].

2.3. Statistical analysis

Scores for the electronically administered BREAST-Q were computed for each scale of the three procedure-specific modules on the basis of the BREAST-Q scoring tables. Scores were excluded