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Breast Cancer and Reconstruction: Normative Data for Interpreting the BREAST-Q

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Abstract

Background—The BREAST-Q is a patient-reported outcome instrument used to evaluate outcomes in patients undergoing breast cancer surgery and reconstruction. Normative values for the BREAST-Q breast cancer modules have not been established, limiting data interpretation.

Methods—Participants were recruited via the Army of Women, an online community of women (with and without breast cancer), to complete mastectomy, breast conserving therapy (BCT), and reconstruction pre-operative BREAST-Q scales. Inclusion criteria were women aged ≥18 years without a prior history of breast surgery or breast cancer. Analysis included descriptive statistics, a linear multivariate regression, and a comparison of the generated normative data to previously published BREAST-Q findings.

Results—The BREAST-Q was completed by 1,201 women. Mean age was 54 ±13 years, mean body mass index (BMI) 26 ±6, and 38% (n=455) had a bra cup D. Mean scores for BREAST-Q scales (±standard deviation) were as follows: Satisfaction with Breasts (58 ±18), Psychosocial Well-being (71 ±18), Sexual Well-being (56 ±18), Physical Well-being-Chest (93 ±11), and Physical Well-being-Abdomen (78 ±20). Women with BMI ≥30, cup size D, age <40, and income <\$40,000/year reported lower scores. Comparing normative scores to published data in breast cancer patients, Satisfaction with Breasts were higher after autologous reconstruction and

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lower after mastectomy, Sexual Well-being scores were lower after mastectomy and BCT, and Physical Well-being Chest scores were lower after mastectomy, BCT and reconstruction.

Conclusions—These are the first published normative scores for the BREAST-Q breast cancer modules, and provide a clinical reference point for the interpretation of data.

Introduction

Each year 230,000 women in the United States are diagnosed with invasive breast cancer (1-3). For women with early stage invasive breast cancer, 36% undergo mastectomy and for women with advanced stage, 58% undergo mastectomy (4). After mastectomy, the overall rate of breast reconstruction has been reported at 42%, which includes 25% of patients beginning reconstruction at the time of mastectomy, and 17% undergoing delayed reconstruction after the completion of cancer treatment (5). While not desired by or available to all women, breast reconstruction for women with breast cancer is well established, and has demonstrated improved patient outcomes in comparison to mastectomy alone (5-8).

Breast reconstruction is a relatively safe procedure. The primary goal is to improve quality of life (QOL) and breast-related satisfaction. While traditional surgical outcomes such as morbidity and mortality are important in evaluating these patients, patient-reported outcome (PRO) instruments that assess outcomes related to satisfaction and QOL are often of more relevance. One of the most widely used PRO instruments is the BREAST-Q (9).

The BREAST-Q is a validated, rigorously developed PRO instrument specific to breast surgery. The BREAST-Q has been used in over 22,000 patients undergoing breast surgery, including breast reconstruction, augmentation and reduction (9-14). Relevant to breast cancer, there are BREAST-Q modules specific to mastectomy, breast conserving therapy (BCT), and breast reconstruction. Each module has pre- and post-operative scales. There are four scales common to all pre-operative modules for breast cancer and reconstruction patients: Satisfaction with Breasts, Psychosocial Well-being, Sexual Well-being, and Physical Well-being. The Reconstruction module additionally has Physical Well-being Abdomen for use in autologous reconstruction patients. Each scale is scored to generate a numerical score on a scale from 0 (worst) to 100 (best), which can then be used to compare patients undergoing different procedures or at different pre- and post-operative time points. The BREAST-Q has been in use since its inception in 2009 and has led to important findings related to breast surgery.

A current limitation of the BREAST-Q is a lack of normative values. It is not yet known how patients who are presenting for and undergoing breast cancer resection and reconstruction compare to a population control. This limits both our interpretation of BREAST-Q data as well as our ability to fully qualify the impact of breast cancer and breast reconstruction on individuals. The primary aim of this study was to determine population norms for the BREAST-Q Reconstruction module. These normative values will be applicable to the Mastectomy, BCT, and Reconstruction modules. The secondary aim was to compare these generated population norms to previously published findings describing outcomes in women undergoing breast cancer treatment and reconstruction.

Methods

Study Population

Participants were recruited via the Army of Women (AOW), an online community of women, with and without breast cancer, started in 2008 by the Dr. Susan Love Research Foundation, with a mission to promote breast cancer research. Inclusion criteria were female gender, age 18 years or older, no prior history of breast cancer or breast surgery, and the ability to complete an online questionnaire in English. Prior to recruitment, the study was accepted by the Scientific Advisory Committee at the AOW, and Dartmouth College's Committee for the Protection of Human Subjects granted an IRB waiver.

Recruitment

An electronic recruitment email (e-blast) was sent to 121,688 AOW members with a short description of the study and the eligibility stated above. AOW members interested in participating self-selected to complete the study based on the inclusion criteria. Data was collected using Qualtrics, a web-based software for questionnaire administration (Provo, UT; www.qualtrics.com). Recruitment was part of a larger study to generate normative scores for the breast cancer (Mastectomy, BCT, Reconstruction), Augmentation and Reduction BREAST-Q modules. Participants completed one of the three BREAST-Q modules along with demographic information, bra cup size, height, and weight. Participants did not know which BREAST-Q module was being completed. Data collection for the three modules was completed in a step-wise fashion, with an algorithm in the e-blast hyperlink automatically rerouting participants to the next BREAST-Q module once 1,200 participants had completed the prior module. Normative values for the Reduction and Augmentation modules will be published separately.

BREAST-Q

The BREAST-Q is a rigorously developed, well-validated, breast surgery-specific PRO instrument that has been administered to over 22,000 women, making it one of the most widely used breast surgery specific PRO instruments (9-15). Published in 2009 following internationally accepted guidelines for PRO development, the BREAST-Q has modules designed specifically for the evaluation of outcomes in women undergoing mastectomies, BCT, and breast reconstruction (9, 11, 16, 17). The conceptual framework and set of scales were developed from a literature review, patient interviews (n=48), cognitive patient interviews (n=46), and expert opinion from healthcare professionals, including plastic surgeons. Prior to publication of the finalized instrument, the BREAST-Q was administered to 2715 patients, including 908 pre-surgery patients and 1807 post-surgery patients. The Reconstruction module had Cronbach's alpha scores 0.88 to 0.96, item total correlations 0.56 to 0.86, and test-retest reliability with intraclass correlation coefficients 0.93 to 0.96. The BREAST-Q breast cancer modules have 4 pre-operative scales: Satisfaction with Breasts (n=4 items), Psychosocial Well-being (n=10 items), Sexual Well-being (n=6 items), and Physical Well-being Chest (n=16 items), and the Reconstructive pre-operative module additionally has Physical Well-being Abdomen (n=5 items). Responses on each scale are summed and then transformed using Q-Score (New York, NY; <https://webcore.mskcc.org/breastq/scoring.html>) to a scale from 0 (worst) to 100 (best).

Data Analysis

Data analysis included descriptive statistics and a backward-selection linear multivariate regression to identify which variables were associated with BREAST-Q scores. Computed descriptive statistics included mean, standard deviation, 95% confidence intervals (CIs) for continuous variables, and percentages for categorical variables. Continuous and categorical non-dichotomous variables were transformed into dichotomous variables for the multivariate regression analysis as follows: body mass index (BMI) ≥ 30 vs. BMI <30 , age ≥ 40 vs. age <40 , bra cup size $\geq D$ vs. $<D$, ethnicity white non-Hispanic vs. all others, education to college degree or higher vs. less than college degree, employment to full-time vs. other than full-time, income $\geq \$40,000$ vs. $<\$40,000$ /year, and marital status to married (including living with significant other) vs. other. Binomial variables with a probability of less than 0.2 were rejected and removed from the model, and the model was rerun with only significant variables ($p<0.05$) included. Data analysis was performed using Stata/SE 11.0 (College Station, Texas).

Using the AOW normative data generated in this study, a separate descriptive analysis compared these data to previously published BREAST-Q data. Studies were identified by a literature search in July 2016 in PubMed, with “BREAST-Q” and “BREASTQ” as search terms. Identified studies were manually evaluated for use of the Mastectomy, BCT, and Reconstruction module. Data extracted from each publication included study design, sample size, and BREAST-Q scores, with sample size and BREAST-Q mean score and standard deviation used to calculate a 95% CI. Additional information was requested from authors as needed. There are no published guidelines regarding minimal clinically important differences for the BREAST-Q Reconstruction module. A difference of 0.5 standard deviations was utilized for the BREAST-Q Augmentation module (18), and thus we adopted a difference of 0.5 standard deviations of our normative scores, for analyzing the differences between normative scores and published data.

There were 74 identified studies utilizing the BREAST-Q Reconstruction module for evaluating outcomes in women undergoing mastectomy, BCT and/or reconstruction. There were no published studies with available data specifying use of either the Mastectomy or BCT modules, rather the BREAST-Q Reconstruction module was used to capture outcomes in these patients. Studies were selected that had large sample sizes with authors contacted for missing data. To compare outcomes in patients after mastectomy, a recent study by Ng et al. reporting on 79 post-mastectomy patients was selected (19). To compare findings after BCT, a study by Howes et al. describing post-operative findings at a mean post-operative time of 2.4 years after BCT ($n=97$) was selected (20). Data from the Mastectomy Reconstruction Outcomes Consortium (MROC) Study was selected for reconstruction patients. Pre-operative ($n=1996$) and one-year post-operative ($n=1688$) data in women with implant reconstruction, as well as pre-operative ($n=950$) and one-year post-operative ($n=809$) data in women with autologous reconstruction were reported (21).

Results

The e-blast was circulated to the 121,688 active AOW members in August 2015. To recruit the remaining 409 participants to complete 3,600 participants across all three BREAST-Q

modules, a second e-blast was circulated in November 2015. A total of 4,326 women self-selected to meet inclusion criteria, and 3,618 women completed one of the three pre-operative BREAST-Q modules. After meeting capacity, an additional 142 women attempted to complete the study prior to the study closing via the AOW. The total response rate was 87%, with 1,201 of the participants completing the pre-operative breast cancer modules.

Specific to the breast cancer and reconstruction sample, mean age was 54 ± 13 years, mean BMI was 26 ± 6 , and 38% had a bra cup size D or greater ($n=455$). The majority of participants were non-Hispanic White (92%, $n=1097$). Additionally, 68% were married ($n=818$). The full demographic data are listed in Table 1. Normative scores are listed in Table 2. Of note, 85% of participants ($n=1018$) completed the Sexual Well-being Instrument. Consistent with instructions in the BREAST-Q based on patient feedback, study participants were specifically instructed not to complete items in the Sexual Well-being scale if they felt the content was not applicable to them, or they felt uncomfortable with the subject matter.

Using 95% CIs, the linear multivariate regression was used to identify variables (age, BMI, bra cup size, income, marital status) across the five breast cancer scales associated with BREAST-Q scores, see Figure 1. Women with BMI ≥ 30 , cup size $\geq D$, age <40 , and income $< \$40,000/\text{year}$ had lower scores for the breast cancer modules when compared to a reference group of women without those demographic and body size variables.

The comparison between the previously published mastectomy and BCT data and normative BREAST-Q scores using 95% CIs are shown in Figures 2 and 3. In comparison to the normative AOW values, patients at a mean 2.4 years post-mastectomy demonstrated lower Satisfaction with Breasts, Sexual Well-being, and Physical Well-being Chest scores. After BCT, patients demonstrated lower Sexual Well-being and Physical Well-being Chest scores in comparison to the AOW norms.

The comparison between the pre- and one year post-operative MROC data and normative BREAST-Q scores using 95% CIs are demonstrated in Figure 4a and 4b. Physical Well-being Chest scores were lower than normative values in the pre- and post-operative groups for autologous and implant-based reconstruction. Higher post-operative scores were reported for Satisfaction with Breasts both in comparison to pre-operative values and the AOW normative scores after autologous reconstruction. Autologous reconstruction was also associated with an increase in Psychosocial Well-being and a decrease in Physical Well-being Abdomen between pre- and post-operative patients.

Discussion

Breast cancer has the highest incidence of any cancer in the United States, although fortunately with a comparatively low mortality rate (22). In the setting of lower mortality, issues of satisfaction and QOL are of increased importance in evaluating outcomes in this population. To this end, PRO questionnaires, such as the BREAST-Q, that capture the impact of breast cancer surgery and reconstruction on breast-related satisfaction and QOL play a key role in helping to understand the burden of disease and in shaping clinical

practice. Since inception in 2009, the BREAST-Q has been used to demonstrate many key findings in this patient population.

The BREAST-Q has shown the impact of breast reconstruction on PROs and the value of reconstruction after mastectomy. In one of the earliest studies using the BREAST-Q to examine the differences in PROs between women undergoing mastectomy alone versus reconstruction, Eltahir et al. demonstrated lower BREAST-Q scores for Satisfaction with Breasts, Psychosocial Well-being, and Sexual Well-being in women after mastectomy alone versus mastectomy with reconstruction (23). These findings have been replicated in multiple subsequent studies (19, 20, 24, 25), including a prospective study by Chao et al. that demonstrated lower Satisfaction with Breasts, Psychosocial Well-being, Sexual Well-being, and Physical Well-being Chest in patients undergoing mastectomy alone versus mastectomy with reconstruction (26). While BREAST-Q outcomes following BCT are not as well established, Satisfaction with Breasts scores after BCT with various incision techniques have been reported, along with findings of higher scores associated with lower quantities of resected tissue and scores associated with BCT lower than reconstruction yet higher than mastectomy alone (20, 27-29).

In patients who undergo reconstruction, autologous reconstruction has been associated with higher Satisfaction with Breasts, Psychosocial Well-being, and Physical Well-being in comparison to implant-based reconstruction (30-34). Additionally, in implant-based reconstruction, the BREAST-Q has been used to demonstrate superior PRO scores when using silicone in comparison to saline implants for reconstructive as well as cosmetic augmentation purposes (35-38).

The findings discussed above are important and many have impacted patterns of care as well as third-party reimbursement. However, a key limitation to the current literature is how women not undergoing breast cancer treatment or breast reconstruction report breast satisfaction and breast-related QOL. The normative data generated here provides clinical context and a reference point to interpreting BREAST-Q scores going forward.

In the literature, patients undergoing mastectomy alone have been shown to have lower BREAST-Q scores for all four pre-operative scales: Satisfaction with Breasts, Psychosocial Well-being, Sexual Well-being, and Physical Well-being, when compared to women after reconstruction (19, 20, 23-26). In the data published by Ng et al., Psychosocial Well-being is not less than 0.5 standard deviations below the norm (19). This finding suggests that while mastectomy alone may impact Psychosocial Well-being in a negative way, these women do not report lower levels of overall emotional wellness, self-confidence, and/or body acceptance in comparison to a normative population.

In the data published by Howes et al., BREAST-Q scores were highest in those women undergoing reconstruction, followed by BCT, and then mastectomy alone (20). When comparing the reported BCT scores to normative data, only Sexual Well-being and Physical Well-being Chest are lower than 0.5 standard deviations below the norm. This suggests that while overall women may be less satisfied with BCT in comparison to mastectomy with

reconstruction, this is of most clinical relevance when discussing sexual and physical well-being.

The literature has demonstrated that women who undergo autologous reconstruction have improved satisfaction and QOL in comparison to women with implant-based reconstruction (30, 32, 33). The normative values generated here provide increased clinical relevance to this finding. In the MROC study, only patients with autologous reconstruction had Satisfaction with Breasts scores above the norm, suggesting that the other differences between autologous and implant-based reconstruction may not be of the same clinical relevance. However, perhaps of greater importance, the MROC data also demonstrates that both implant and autologous breast reconstruction are associated with post-operative scores at or above the normative level. Having a normative reference point gives greater meaning to changes in the BREAST-Q than purely the comparison of pre- and post-op data points. Pre-operative patients are not “normal,” as they have undergone the physical and psychological trauma associated with being diagnosed with breast cancer, changes captured in the BREAST-Q. Breast reconstruction can now be associated with a “return to normalcy,” a clinically relevant finding, and a finding that mastectomy alone has not demonstrated.

Women in all three studies used for comparison had Physical Well-being scores below the norm. Pre-operative scores may be explained by pain secondary to the tumor itself, or pain after biopsy prior to cancer resection. Post-operative scores may be explained by a multitude of factors including the resulting scar, damage to the pectoralis major muscle, capsular contracture, and physical limitations after breast surgery or reconstruction.

Within our normative population there were factors associated with differences in generated normative BREAST-Q scores. Women with a larger BMI and bra cup size had lower breast satisfaction and breast-related QOL. Alternatively, women who were older had higher breast satisfaction and breast-related QOL. These factors may impact the interpretation of normative values in these patient populations.

This study has several advantages. This is the first study to generate normative values for the BREAST-Q Reconstructive module. These normative scores may be used for the Satisfaction with Breasts, Psychosocial Well-being, Sexual Well-being, and Physical Well-being scales within the BREAST-Q Mastectomy, BCT, or Reconstruction modules. These normative scores will be useful in direct clinical care, research, and health-policy. Furthermore, these normative values were generated from a large patient sample of over 1,200 women with a diversity of age, breast cup size and BMI, to match the diverse population of women undergoing breast cancer treatment and reconstruction.

Limitations of this study primarily relate to the population of women utilized to generate the normative data. The AOW population is primarily Caucasian and composed of women with higher than average levels of education and income. While this is consistent with the demographics of the majority of the literature utilizing the BREAST-Q, this is certainly not representative of all women in the United States who have been diagnosed with breast cancer. Additionally, women completed the study online without study personnel confirming their eligibility. The authors did not screen patients individually for a history of breast cancer

or breast surgery, and it is possible that some respondents failed to exclude themselves based on exclusion criteria, thus biasing the results. Also, we did not know the number of women enrolled in the AOW who met inclusion criteria at the time of our study. We therefore calculated our response rate of 87% based on the number of women who confirmed eligibility for the study. As it is possible that there were additional women in the AOW who met inclusion criteria and not interested in participating, our response rate may be overestimated. Additional limitations relate to the use of the previously published datasets, including limited follow-up time, and lack of pre-operative data. Lastly, the published literature describing results in the mastectomy and BCT population used the Reconstructive module, instead of the Mastectomy and BCT modules, which have slightly different post-operative scales.

The normative values for the BREAST-Q generated here have significant implications for future research and clinical care. As discussed above, the ability to compare BREAST-Q scores with the norm helps to demonstrate the significance of a given difference in BREAST-Q scores between different patient populations. Normative values also contribute to our understanding of the impact breast cancer and breast reconstruction has on individuals. One example of this is the impact breast cancer and reconstruction has on Physically Well-being of the Chest. This deviation from the norm would not have been appreciated without a normative reference point.

Conclusion

Outcomes in patients undergoing breast cancer treatment and reconstruction are often evaluated with PRO instruments, such as the BREAST-Q. PRO instruments generate useful data regarding breast satisfaction and breast-related QOL. This study presents the first known normative values for the BREAST-Q. These normative scores will be useful for clinicians and researchers in providing a clinical context to interpret BREAST-Q data.

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Figure 1. BREAST-Q Breast Cancer Modules: Demographic Variables with 95% Confidence Intervals

- Purple line = mean score with 95% confidence intervals in brackets

Figure 2. BREAST-Q Mastectomy Module Normative Scores vs. Previously Published Post-Operative Mastectomy Scores with 95% Confidence Intervals

Figure 3. BREAST-Q Breast Conserving Therapy Normative Scores vs. Previously Published Post-Operative Breast Conserving Therapy Scores with 95% Confidence Intervals

Figure 4.

a. BREAST-Q Reconstruction Normative Scores vs. Previously Published Scores with 95% Confidence Intervals: Implant-based Reconstruction

b. BREAST-Q Reconstruction Normative Scores vs. Previously Published Scores with 95% Confidence Intervals: Autologous Reconstruction

Table 1
BREAST-Q Reconstruction Module Demographics

	Number	Percentage
Sample Size	1201	
Age in years: mean $\pm$ SD	54 $\pm$ 13	
BMI: mean $\pm$ SD	26 $\pm$ 6	
Bra Size		
<A	15	1%
A	94	8%
B	307	26%
C	324	27%
D	217	18%
DD	155	13%
>DD	83	7%
Ethnic/cultural group		
South Asian or East Indian	1	0.1%
Asian or Pacific Islander	11	1%
Black Non-Hispanic	11	1%
Black Hispanic	0	0.0%
White Non-Hispanic	1097	92%
White Hispanic	39	3%
Native Canadian/American	20	2%
Other	15	1%
Education		
Some High School	2	0.2%
High School Diploma	35	3%
Some College, Trade or University	158	13%
College, Trade or University Diploma	445	37%
Some Master or Doctoral	96	8%
Master or Doctoral Degree	463	39%
Employment		
Full Time	530	44%
Part Time	154	13%
Voluntary Work	28	2%
Homemaker	117	10%
Student	20	2%
Retired	288	24%
Unable to Work or Disabled	12	1%
Unemployed or Seeking Employment	28	2%
Other	22	2%
Annual Gross Household Income		

	Number	Percentage
<\$20,000	29	3%
\$20,000 - \$39,999	116	10%
\$40,000 - \$59,999	157	14%
\$60,000 - \$79,999	174	15%
\$80,000 - \$99,999	165	14%
\$100,000	506	44%
Marital Status		
Married	818	68%
Living with Significant Other	82	7%
Widowed	49	4%
Separated	16	1%
Divorced	100	8%
Single, Never Married	134	11%

SD = standard deviation

Table 2
BREAST-Q Reconstruction Module Normative Scores

	N	Mean	SD
Satisfaction with Breasts	1200	58	18
Psychosocial Wellbeing	1199	71	18
Sexual Wellbeing	1018	56	18
Physical Wellbeing Chest	1199	93	11
Physical Wellbeing Abdomen	1199	78	20

N = number; SD = standard deviation