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BREAST-Q Breast-Conserving Therapy Module: Normative Data from a Dutch Sample of 9059 Women

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Background: BREAST-Q, a patient-reported outcome measure for cosmetic and reconstructive breast surgery, is widely used in both clinical research and practice. The aim of this study was to acquire normative data of BREAST-Q's Breast-Conserving Therapy Module from a Dutch population sample and to compare it with existing normative BREAST-Q values.

Methods: Flyers with QR codes, WhatsApp, and one academic center's Facebook and LinkedIn platforms were used to direct participants to self-complete an online version of four domains of the preoperative BREAST-Q Breast-Conserving Therapy Module. BREAST-Q domain scores were log transformed to normalize the distribution. Univariable regression analyses were used to assess (nonlinear) associations between age and BREAST-Q domain scores.

Results: Overall, 9059 questionnaire responses were analyzed. Median (\pm SD) BREAST-Q domain scores were 64.0 ± 18.0 (satisfaction with breasts), 69.0 ± 21.0 (psychosocial well-being), 92.0 ± 20 (physical well-being), and 59.0 ± 15.0 (sexual well-being). Age as a linear term was associated with log-transformed satisfaction with breasts, psychosocial well-being, and physical well-being; sexual well-being was a quadratic function of age. Previous breast surgery unrelated to breast cancer was a significant predictor for higher log-transformed satisfaction with breasts ($\beta = 0.04$, $p < 0.001$) and higher sexual well-being score ($\beta = -0.05$, $p < 0.001$). Compared with previously published normative data, small differences were found in mean BREAST-Q domain scores (mean differences ranging between 2.45 and 6.24).

Conclusions: Normative Dutch BREAST-Q scores follow similar patterns across domains in comparison with previously published normative data. Normative Dutch BREAST-Q data enable future comparisons in breast-related satisfaction and quality of life issues of Dutch patients with breast cancer compared with their age-matched peers. (*Plast. Reconstr. Surg.* 150: 985, 2022.)

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Approximately 17,000 women are diagnosed with breast cancer each year in the Netherlands, 90 percent of whom receive surgical treatment.^{1,2} As the survival rates of patients with early-stage breast cancer have improved considerably in the Netherlands,^{3,4} increasingly more

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attention is being paid to health-related quality-of-life issues within this population.⁵ Patients with breast cancer often experience considerable burden related to numerous physical symptoms, psychosocial distress, and impaired function during and after treatment.^{6,7} Clinicians have increasingly become more aware of the importance of the patient perspective on surgical outcomes, with the goal to improve the quality of clinical breast cancer care.^{8,9}

BREAST-Q, published in 2009, is a well-validated, multiscale, widely used patient-reported outcome measure for women undergoing breast surgery.¹⁰ This condition-specific questionnaire measures the effect of oncologic or reconstructive breast surgery on different health-related quality-of-life domains and has been used in a plethora of scientific publications in the past decade.¹¹ The use of patient-reported outcome measure scores in breast cancer care may improve patient-provider communication,¹² enhance shared decision-making, and manage patients' expectations by informing them on the experiences of past patients.¹³ In addition, as the use of patient-reported outcome measures in breast cancer clinical trials continues to rise, the availability of normative data may be helpful in enabling the interpretability and comparability of patient-reported outcome measure scores across different trial arms.

It has become clear that normative scores are needed to fill the knowledge gap in the interpretation of patient-reported outcome measures, especially to provide context for the interpretation of patient scores following various treatment strategies. Normative data describe outcomes of a defined population without the specific condition of interest.¹⁴ Available normative BREAST-Q data have been published in two studies, both using samples of U.S. women with no previous history of breast cancer or breast surgery.^{15,16} The aim of this study was to collect and describe normative BREAST-Q data from a Dutch sample and compare them with internationally published normative values.

METHODS

Web-Based Questionnaire

An anonymous opt-in web-based questionnaire was developed in LimeSurvey, a secure online survey tool provider.¹⁷ This questionnaire contained the BREAST-Q and additional questions regarding age and history of breast cancer or breast surgery. The questionnaire was prefaced with a study information sheet and a consent statement box to check.

BREAST-Q, developed at Memorial Sloan Kettering Cancer Center (New York, N.Y.), is a surgery-specific instrument that assesses patient satisfaction and health-related quality of life in women undergoing different types of breast surgery.¹⁰ Current BREAST-Q modules include Augmentation, Reduction/Mastopexy, and Breast Cancer, which includes scales for Mastectomy, Reconstruction, Breast Reconstruction Expectations, and Breast-Conserving Therapy.¹⁸

The current study used the second version (published in November of 2017) of the preoperative scale of the BREAST-Q Breast-Conserving Therapy Module. This module contains nine domains, of which three quality-of-life domains [physical well-being (10 items), psychosocial well-being (10 items), sexual well-being (six items)] and one satisfaction domain [satisfaction with breasts (four items)] were administered to participants in this study. Each scale is independent and all items are scored on a Likert scale. According to the BREAST-Q protocol,¹⁸ the total score of each domain is transformed separately using a Rasch model to a number within the range of 0 to 100. A higher score means higher satisfaction or better health-related quality of life.

The Dutch version was translated (both forward and backward translation) by a local academic before conception and design of this study.¹⁸

Recruitment of Study Participants and Data Collection

Three survey distribution techniques were chosen to reach as many potential respondents as possible. First, digital and printed notifications with a QR code hyperlink (to the web-based questionnaire) were distributed by medical students in the city center of Rotterdam for 6.5 days. Second, members of the research team disseminated the hyperlink to friends and family and invited them to share it with others. Third, after a formal request was submitted, the Erasmus University Medical Center posted the survey link on its public Facebook and LinkedIn platforms. The status could be viewed and shared by people who are followers of the academic center's platforms.

Participants were required to self-complete this questionnaire on the recruitment website of the Erasmus MC after reading the study information and giving informed consent. Participants were not compensated and those who failed to complete the questionnaire did not receive a reminder. Data were collected from January through July of 2020 and stored in the LimeSurvey database. Participants who did not finish or submit the questionnaire, reported breast cancer in their history,

or had discrepant responses (mastectomy reported in the history but no breast cancer reported) were not included in the analysis (Fig. 1).

Statistical Analysis

Descriptive statistics, including medians and interquartile ranges, were calculated to present the normative BREAST-Q data. The Mann-Whitney *U* test (nonparametric) was performed to compare BREAST-Q domain scores between women with and without non-breast cancer-related surgery in their history. Skewness and kurtosis were calculated, with significant *p* values rejecting the null hypothesis for all domains. Therefore, natural log transformation was applied for all domain scores to normalize the distribution. Univariable models for each BREAST-Q domain were used to test for non-linearity of the effect of age by comparing models with age as a linear versus age as a quadratic term. In addition, multivariable linear regression analysis was used to analyze whether there was a significant association between age and previous breast surgery unrelated to breast cancer (e.g., surgery for fibroadenoma, cosmetic surgery) and (log-transformed) BREAST-Q domain scores. Cases that contained one or more missing items in a domain of the preoperative BREAST-Q version were excluded from analysis for that subscale. A *t* test was used to compare means and standard deviations of the current study’s normative scores with previously published normative data. Two-sided *p* values less than 0.05 were considered statistically significant.

Statistical analyses were performed using SPSS, version 25.0 (IBM Corp., Armonk, N.Y.).

Anonymized data and syntax of statistical analyses that support the study findings are available from the principal investigator upon reasonable request.

Ethical Considerations

Formal approval from the local medical ethics review committee was not required because the Dutch Medical Research (Human Subjects) Act does not apply to this study. The legal team and department of communications of the Erasmus University Medical Center approved dissemination of the survey link on the institution’s social media platforms.

RESULTS

Study Participants

In total, 9059 questionnaire entries were analyzed (Fig. 1). Mean (\pm SD) age of the overall group was 44 ± 13 years, with most respondents representing the 40 to 49 and 50 to 59 years age groups (Table 1). Eighty-one respondents (0.9% percent) did not complete the items of the sexual well-being domain. All other BREAST-Q domains were completed fully.

Dutch Normative BREAST-Q Scores

Overall, the median (\pm SD) BREAST-Q domain scores were 64.0 ± 18.0 (satisfaction with

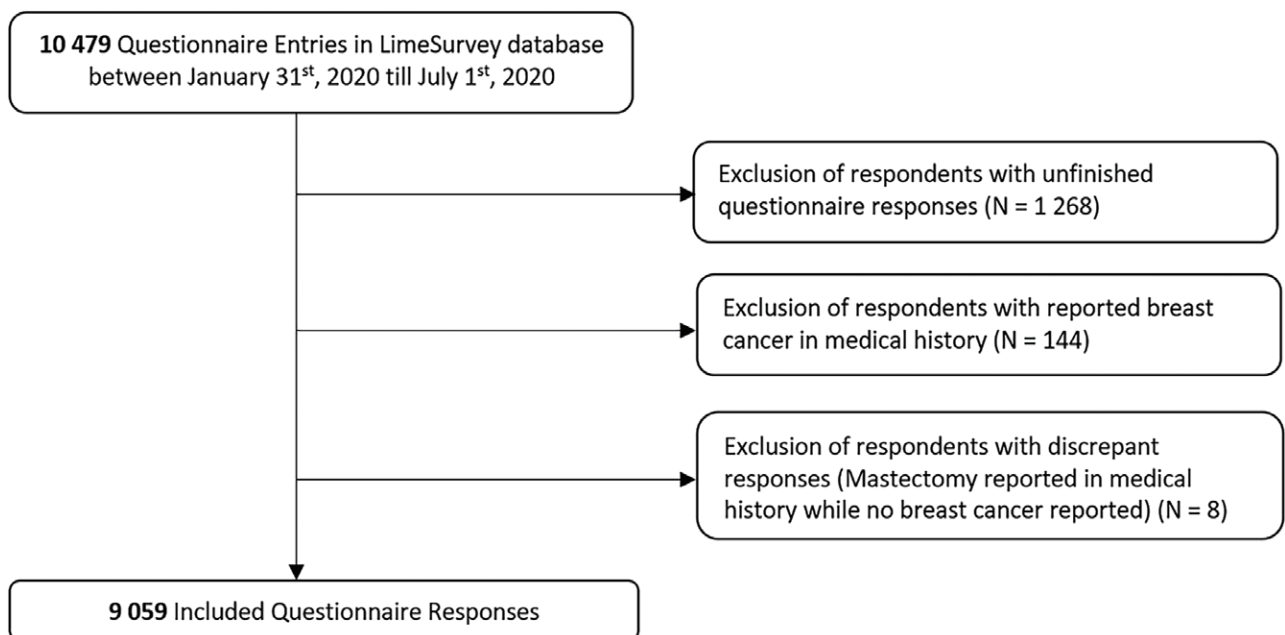


Fig. 1. Flowchart of respondent selection.

Table 1. Respondent Characteristics (n = 9059), January through July of 2020

Characteristics	No. (%)
Age	
18–29 years	1385 (15.3)
30–39 years	1776 (19.6)
40–49 years	2482 (27.4)
50–59 years	2424 (26.8)
60–69 years	837 (9.2)
70 years or older	155 (1.7)
Previous surgery not related to breast cancer	
Breast-conserving therapy (indication: fibroadenoma)	22 (3.1)
Breast reconstruction (cosmetic)	86 (12.2)
Other	682 (96.7)

breasts), 69.0 ± 21.0 (psychosocial well-being), 89.54 ± 12.48 (physical well-being), and 60.38 ± 15.37 (sexual well-being). Median BREAST-Q domain scores stratified by age group can be found in the Supplementary Material. [See **Table, Supplemental Digital Content 1**, which shows BREAST-Q scores (median with interquartile range) stratified by age group, <http://links.lww.com/PRS/F399>.] When comparing patients with ($n = 705$) versus without previous breast surgery unrelated to breast cancer ($n = 8354$), satisfaction with breasts was significantly higher (66.46 ± 20.26 versus 64.05 ± 18.44 ; $p = 0.002$) and physical well-being was significantly lower (86.60 ± 14.26 versus 89.79 ± 12.29 ; $p < 0.001$) for patients who had previous breast surgery.

Univariable Regression Analyses

Testing for linearity revealed age to be linearly associated with log-transformed satisfaction with breasts ($\beta = -0.001$; $p < 0.001$), psychosocial well-being ($\beta = 0.001$; $p < 0.001$), and physical well-being ($\beta = 0.001$; $p < 0.01$), whereas sexual well-being ($\beta = -3.7 \times 10^{-5}$; $p < 0.05$) was found to be a quadratic function of age (Fig. 2). The model identified 34 years as the inflection point at which sexual well-being values began to decrease.

Multivariable Regression Analyses

Multivariable linear regression analyses (Table 2) confirmed age to be a significant predictor for log-transformed satisfaction with breasts ($\beta = -0.001$; $p < 0.001$), psychosocial well-being ($\beta = 0.001$; $p < 0.001$), and physical well-being ($\beta = 0.001$; $p < 0.001$). Whereas previous breast surgery unrelated to breast cancer was positively associated with log-transformed satisfaction with breasts ($\beta = 0.04$; $p < 0.001$), it had a negative association with physical well-being ($\beta = -0.05$; $p < 0.001$).

Comparison with Past Normative BREAST-Q Studies

Figure 3 demonstrates the variation in mean normative BREAST-Q domain scores between the current study and two internationally published studies by Mundy et al.¹⁶ and Klifto et al.¹⁵ on normative data of the BREAST-Q Reconstruction Module.

Normative scores for satisfaction with breasts were significantly higher in the current study compared with Mundy et al.¹⁶ (mean difference, 6.24; $p < 0.001$) and Klifto et al.¹⁵ (mean difference, 4.94; $p < 0.001$), as well as for sexual well-being compared with Mundy et al.¹⁶ (mean difference, 4.38; $p < 0.001$) and Klifto et al.¹⁵ (mean difference, 3.78; $p < 0.001$). A significant score difference for psychosocial well-being was found between the current study and Klifto et al.¹⁵ (mean difference, 2.45; $p < 0.01$). Normative scores for physical well-being were lower compared with Mundy et al.¹⁶ (mean difference, 3.46; $p < 0.0001$) but higher compared with Klifto et al.¹⁵ (mean difference, 5.45; $p < 0.001$).

In contrast to the current study ($\beta = 0.001$; $p = \text{NS}$), Klifto et al.¹⁵ found increasing age to be significantly associated with lower sexual well-being scores ($\beta = -0.3$; $p = 0.018$). Mundy et al.¹⁶ demonstrated younger age (less than 40 years) to be associated with lower physical well-being scores; the current study also revealed a minimal trend toward lower physical well-being scores in the younger age groups (Table 2).

DISCUSSION

Because a breast cancer diagnosis has significant effects on women, both psychologically and physically,¹⁹ it is essential that there are baseline scores available representative of women's quality of life before a potential cancer diagnosis. The BREAST-Q Preoperative Module was originally considered as an accurate baseline; however, these patients are aware of their underlying disease, which immediately alters self-perception and quality of life.¹⁵ According to normative data, one must take into account the degree of representation of the studied cohort. Previously published norm scores may not entirely reflect the normative scores for Dutch women because of cultural differences between American and Dutch female populations. Thus, the aim of this study was to collect and describe normative BREAST-Q scores from a Dutch sample and to compare them with existing international normative data.

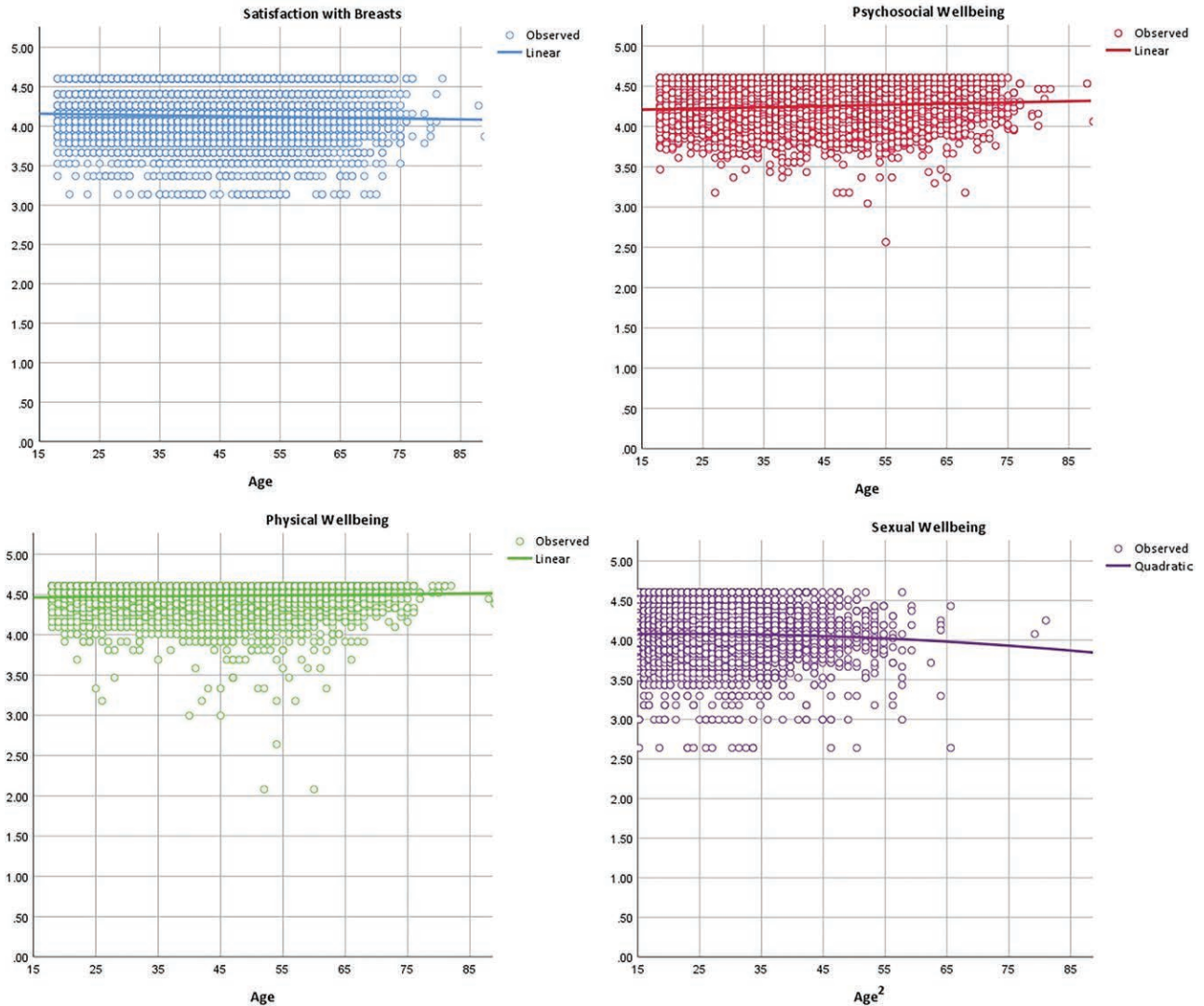


Fig. 2. Univariable regression plots per log-transformed BREAST-Q domain.

Table 2. Multivariable Linear Regression Coefficients for Log-Transformed BREAST-Q Domain Scores

Variables	Satisfaction with Breasts		Psychosocial Well-Being		Physical Well-Being		Sexual Well-Being	
	β	<i>p</i>	β	<i>p</i>	β	<i>p</i>	β	<i>p</i>
Adjusted R^2		0.03		0.07		0.08		0
Age	-0.001	<0.001	0.001	<0.001	0.001	<0.001	0.001	NS
Previous breast surgery unrelated to breast cancer	0.04	<0.001	0.005	NS	-0.05	<0.001	0.014	NS

This study demonstrated through univariable regression analyses a negative linear relation between age and satisfaction with breasts. A positive association was observed between age and psychosocial well-being. Some research has demonstrated higher self-reported body image and self-esteem in middle-aged women compared with younger women,²⁰ partially attributable to less self-objectification,^{21,22} but other studies have concluded

that age alone is not consistently associated with women’s overall body image.²³ This study identified previous breast surgery unrelated to breast cancer to be positively associated with higher satisfaction with breasts. These observations are in concordance with previous studies, which found improved breast satisfaction and quality of life following cosmetic breast surgery.^{24,25} Unsurprisingly, previous breast surgery was associated with lower

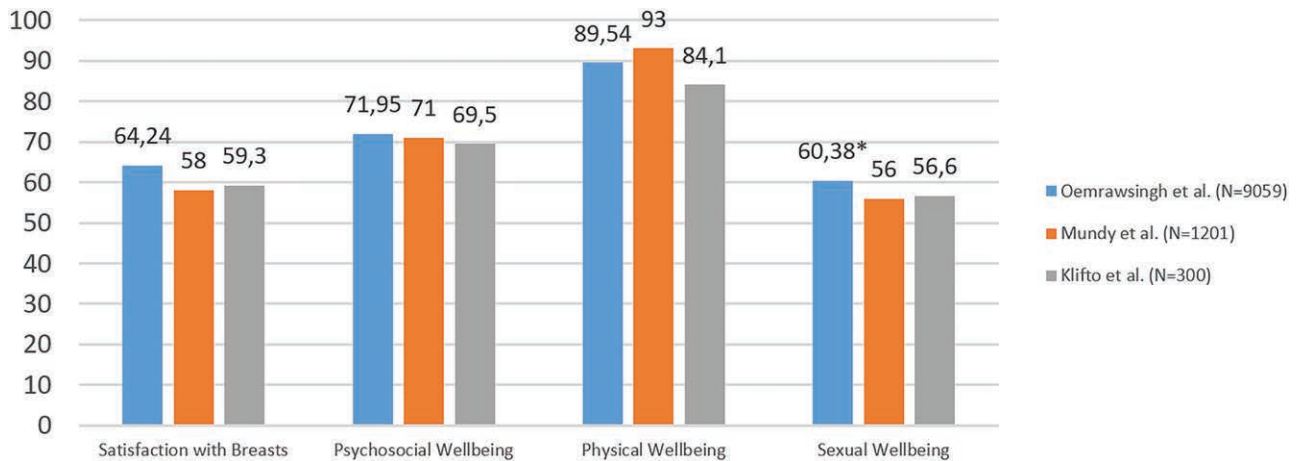


Fig. 3. Variation in normative BREAST-Q domain scores across international publications. *Based on 8978 responses.

physical well-being scores, most likely because of prolonged issues and physical discomfort (e.g., altered breast sensitivity, tenderness). A knowledge gap remains concerning how the strength between age and BREAST-Q domain scores is altered when corrected for other demographic variables. Neither age nor breast surgery unrelated to breast cancer seems to explain much of the variance in BREAST-Q domain scores, as is evident from the low R^2 values.

The current study also compared its normative BREAST-Q domain scores with U.S. scores published by Mundy et al.¹⁶ and Klifto et al.¹⁵ The differences between the current study's normative domain scores and those of the aforementioned studies could be attributable to both methodologic differences and intercultural differences between European and American women in terms of body image or satisfaction with breasts. The normative scores reported by Mundy et al.¹⁶ were based not on a random sample but on the responses of 1201 participants from the Army of Women (now the Love Research Army). The Love Research Army is a strong community that is very aware of breast-related satisfaction and quality of life, possibly influencing responses and thus patient-reported outcome measure scores. The normative values reported by Klifto et al.¹⁵ were obtained at multiple Johns Hopkins clinic sites by recruiting nonpregnant women without a previous history of breast cancer at their routine gynecology appointments. Despite the different population characteristics and methodologies across the three studies (different BREAST-Q scales and different recruitment strategies), there was a similar pattern observed across all BREAST-Q domains among them. This observation suggests that score differences are

most likely attributable to different recruitment strategies, and that, contrary to expectations, intercultural differences in the perception of breast-related quality of life may have minimal influence on the normative scores. Using country-specific normative scores thus may not be necessary, if the assumption is that similar normative scores would be obtained from other Western countries.

Klifto et al.¹⁵ showed a β of -0.3 for the sexual well-being domain in their regression analysis, meaning an increase in age per year results in a 0.3-point decrease in score on a scale from 1 to 100. In the current study, an even smaller and nonsignificant β of 0.001 was observed. Although the result of Klifto et al.¹⁵ was significant, the question arises whether or to what extent such score differences on a scale from 1 to 100 are clinically important. It is thus not only important to take the statistical significance of patient-reported outcome measure score differences between ages into consideration, but also the extent to which these differences are clinically meaningful. To date, there are few publications on minimal clinically important differences in BREAST-Q scores,^{26,27} with varying definitions for minimal clinically important difference being used. Minimal clinically important difference indicates the smallest change in patient-reported outcome measure (domain) score that patients perceive to be important or beneficial and that would justify a change in patient management.²⁷⁻²⁹ Voineskos et al.²⁷ determined, with distribution-based methods, a four-point minimal clinically important difference on the BREAST-Q Reconstruction Module (scale, 0 to 100), based on 3052 patients who underwent breast reconstruction. Minimal clinically important differences are estimates that

are subject to change depending on the study population (e.g., age, body mass index, socioeconomic status, educational background), cultural setting, and patient-reported outcome measure of interest. Future research should focus on calculating and validating minimal clinically important differences for BREAST-Q, as interpretability is a cornerstone in using patient-reported outcome measures for patient-centered care.

Strengths and Limitations

One of the key strengths of this study is the large size of the study sample. After the survey link was posted on the public Facebook and LinkedIn platforms of the Erasmus MC, a tremendous increase in respondents was observed. Because the questionnaire was widely available online and available only in Dutch, the authors assume that respondents represent a heterogeneous Dutch population-based cohort in terms of geographic distribution. Population-based studies are often based on probability samples of a reference population; therefore, the exact sample strategy is important.³⁰ In this study, different recruitment methods were used to maximize the generalizability of the results. Compared with the population statistics in the Netherlands,³¹ both the age distribution and mean age of Dutch women (43.0 years in the population versus 44 years in the study) were similar. Although this study recruited a considerable number of respondents successfully, it is possible that health-conscious women or women with a strongly positive or negative body image were more likely to respond. The anonymity of the questionnaire may have partly remedied this effect but it also may have resulted in higher normative scores. The lack of knowledge of sociodemographic characteristics (e.g., body mass index, family status, educational background, socioeconomic status) of the presented cohort prevents stating with certainty that this study is population-based.

In this sample, 6.8 percent of respondents reported a history of breast surgery not related to breast cancer, assumed to include breast implants, augmentation, reduction, and other cosmetic procedures. Some participants ($n = 22$) self-reported no history of breast cancer but also reported having breast-conserving surgery in the past. This discrepancy may be partially explained by patients being treated for benign tumors such as fibroadenomas. Because these cases also occur in the healthy female population, it still represents a normative cohort. Therefore, it was decided to only exclude patients who reported mastectomy but no history of breast cancer ($n = 8$). There is a possibility that

this small number of patients underwent preventive mastectomy, as approximately 40 percent of Dutch carriers of a breast cancer gene mutation (*BRCA 1/2*) undergo bilateral risk-reducing mastectomy.³² Previous breast surgery unrelated to breast cancer for cosmetic purposes or medical reasons may affect scores differently (for example, in the satisfaction with breasts scale). The possible heterogeneity of the group with previous breast surgery unrelated to breast cancer must be taken into account when interpreting the results.

A limitation of this study was the considerable sample size differences across some age groups, with older age groups (60 years or older) being less represented in this study. For Dutch women receiving a diagnosis of breast cancer, the mean age is 57 to 62 years.^{33,34} The mean \pm SD age for the overall group in our sample was 44 ± 13 years. This can be explained by the large number of respondents in younger age groups, a potential consequence of using social media platforms. Older women may be less active on social media or may not have access to such platforms or a web-based questionnaire. Despite the fact that multiple recruitment methods were used, disproportionate sampling nevertheless emerged. However, the 40 to 49 years and 50 to 59 years age groups were represented by 2482 and 2424 participants, respectively, still providing adequate power for the analyses. Survey data commonly exhibit disproportionate sampling, either as a result of bias in the sampling procedure or by design.³⁵ In this study, the sample size differences between age groups is most likely attributable to the latter. Another limitation was the limited questions that captured respondents' demographic profile. It was decided not to include questions on marital status, educational background, annual income, and occupation, because the authors were mindful of the fact that such sensitive questions can potentially affect survey outcomes by limiting the willingness of participants to complete the survey, the response rates to certain items, and the accuracy of responses.³⁶ As only two covariates (age and previous breast surgery unrelated to breast cancer) were collected and used as predictors for model fitting, no variable selection procedure (e.g., forward or backward selection) was performed. A follow-up study will collect more covariates and proceed with a variable selection procedure to control for possible selection bias. Finally, as with most survey studies, some selection bias may have occurred because of self-selection. In this study, it was not possible to determine the response rate for returned questionnaires as a registration log was not kept for those women who viewed the survey

hyperlink but chose not to open it. It does have to be noted that there were no significant differences in domain scores between patients who completed ($n = 9059$) and those who did not fully complete ($n = 1268$) the questionnaire.

CONCLUSIONS

This study provides age-dependent normative values for BREAST-Q derived from a Dutch sample. These values may provide both clinicians and patients more context when interpreting post-surgical BREAST-Q scores, thereby potentially managing patients' expectations and improving patient-provider communication in the consultation room. This study demonstrated that age alone has a weak association with BREAST-Q domain scores on a scale of zero to 100. Small differences were found between the current study's Dutch normative BREAST-Q scores and previously published US scores, while a similar pattern across domain scores was observed.

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