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Racial and Ethnic Variations in One-Year Clinical and Patient-Reported Outcomes Following Breast Reconstruction

Nicholas L Berlin, MD, MPH[1], **Adeyiza O Momoh, MD**[2], **Ji Qi, MS**[1], **Jennifer B Hamill, MPH**[1], **Hyungjin M Kim, ScD**[2,3], **Andrea L Pusic, MD, MHS**[4], and **Edwin G Wilkins, MD, MS**[1]

[1]Section of Plastic Surgery, University of Michigan, Ann Arbor, MI 48109, USA

[2]Center for Statistical Consultation and Research, University of Michigan, Ann Arbor, MI 48109, USA

[3]Department of Biostatistics, University of Michigan, Ann Arbor, MI 48109, USA

[4]Division of Plastic and Reconstructive Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY 10065, USA

STRUCTURED ABSTRACT

Background—Existing studies evaluating racial and ethnic disparities focus on describing differences in procedure type and the proportion of women who undergo reconstruction following mastectomy. This study seeks to examine racial and ethnic variations in clinical and patient-reported outcomes (PROs) following breast reconstruction.

Methods—The Mastectomy Reconstruction Outcomes Consortium is an 11 center, prospective cohort study collecting clinical and PROs following autologous and implant-based breast reconstruction. Mixed-effects regression models, weighted to adjust for non-response, were performed to evaluate outcomes at one-year postoperatively.

Results—The cohort included 2,703 women who underwent breast reconstruction. In multivariable models, Hispanic or Latina patients were less likely to experience any complications and major complications. Black or African-American women reported greater improvements in psychosocial and sexual well-being.

Conclusions—Despite differences in pertinent clinical and socioeconomic variables, racial and ethnic minorities experienced equivalent or better outcomes. These findings provide reassurance in the context of numerous racial and ethnic health disparities and build upon our understanding of the delivery of surgical care to women with or at risk for developing breast cancer.

Corresponding Author and Request for Reprints: Edwin G Wilkins, MD, MS; Professor, Section of Plastic Surgery, University of Michigan, Ann Arbor, MI 48109, USA. Phone: 734-936-5890; Fax: 734-763-5354.

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Keywords

Breast Reconstruction; Breast Cancer; Outcomes Research; Socioeconomic Factors; Public Health; Patient-Reported Outcomes

INTRODUCTION

Racial and ethnic differences in health care are well documented. The Institute of Medicine (IOM) reviewed health care disparities for racial and ethnic minorities in the landmark report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*.[1] According to the IOM, however, the existence of disparities is still largely unrecognized. Public and professional awareness is an essential starting point for efforts at addressing this issue. In the context of a health care system increasingly focused on equitable and patient-centered care, identifying and eliminating racial and ethnic disparities has become a national priority.

Breast cancer is the most common non-skin cancer among women in the United States.[2] Approximately 1 in 8 women (12%) in the United States will develop invasive breast cancer during their lifetimes.[2] Despite the growing use of breast conservation as the primary therapy for breast cancer, mastectomy remains a common treatment option. For patients who undergo mastectomy, the impact on body image, psychosocial well-being and quality of life can be devastating. [3] Many patients choose to undergo breast reconstruction following mastectomy to decrease the adverse impact of mastectomy on psychosocial functioning. There are well-documented psychological, social, emotional, and functional benefits, including improved psychological health, self-esteem, sexuality, body image and reduced concerns of cancer recurrence.[4–6] Since the passage of the Women's Health and Cancer Rights Act in 1998, a mandate for health insurance coverage of breast reconstruction, the proportion of women who choose to undergo breast reconstruction has dramatically increased.[7,8] In 2015, approximately 106,338 women underwent breast reconstruction in the United States.[9]

Previous studies have focused on describing racial and ethnic differences in the proportion of women who chose to undergo breast reconstruction following mastectomy despite mandated insurance coverage of breast reconstruction.[10,11] Other studies have assessed the role of sociodemographic factors in the type of breast reconstruction chosen.[12–16] These studies have begun to elucidate psychosocial and language barriers related to race and ethnicity that influence access to and utilization of these procedures. However, postoperative outcomes following these procedures based upon race and ethnicity remain understudied. Furthermore, previous studies on this topic have not assessed patient-reported outcomes (PROs) following breast reconstruction. In the context of nationwide focus on patient-centered care and the known psychosocial benefits of breast reconstruction, PROs are now considered fundamental outcome measures following these procedures.[17,18] The objectives of this study were to identify and assess racial and ethnic variations in clinical and patient-reported outcomes following breast reconstruction.

MATERIAL AND METHODS

Data Source and Analytic Cohort

The Mastectomy Reconstruction Outcomes Consortium (MROC) is a multi-institutional prospective cohort study utilizing data collected from a network of 11 leading medical centers in the United States and Canada to compare long-term outcomes for eight commonly used options for breast reconstruction following mastectomy. Data was collected from a variety of sources, including structured surveys and medical records. All women at least 18 years of age who underwent breast reconstruction following mastectomy between years 2012 to 2015 at any of the participating sites, including patients undergoing immediate or delayed procedures and unilateral or bilateral reconstruction, were eligible for recruitment into the study. Women who underwent prophylactic mastectomy, without a prior history of breast cancer, were also eligible to participate. Patients receiving breast reconstruction following breast augmentation, mastopexy (breast lift), or breast reduction, as well as patients undergoing secondary reconstruction following previously failed attempts were excluded from the study due to possible confounding from the prior operations. The population from which participants were recruited reflected the racial and ethnic diversity of the medical centers' service areas, which included urban, rural, academic, and private practice settings.

Independent Variables

Baseline socio-demographic information, including race, ethnicity, age, highest level of education attained, and annual household income were collected from study participants through self-reported structured, web-based surveys administered in the preoperative period. Clinical information, including surgery date, histologic diagnosis, date(s) and sides(s) of mastectomy, date and type of radiation therapy, body mass index, smoking status, and medical comorbidities were collected from electronic medical records. Type of breast reconstruction was categorized as 1) implant-based, procedures, 2) latissimus dorsi myocutaneous flaps, and 3) autologous breast reconstructions, which included all methods of abdominal-based breast reconstruction (free tissue transfer and pedicled myocutaneous flaps) as well as superior and inferior gluteal artery perforator flap procedures.

Race and Ethnicity

For analytic purposes, patient race and ethnicity was categorized into White (non-Hispanic and non-Latina), Black or African-American (non-Hispanic and non-Latina), Hispanic or Latina, or Other (including Asian, Native American/Alaska Native, Native Hawaiian or Other Pacific Islander). A total of seven patients were excluded from the analysis due to missing race and ethnicity information.

Study Outcomes

The primary outcomes of interest included clinical outcomes and PROs at one-year following breast reconstruction. Clinical outcomes were defined separately as the occurrence of any complication, at least one major complication, or breast reconstruction failure. Major complications were defined as complications requiring unplanned readmission or

reoperation. Reconstructive failure was defined as a complication resulting in removal of an implant or flap. Measures of PROs included four domains of the BREAST-Q Reconstructive Module (satisfaction with breasts, psychosocial well-being, physical well-being, and sexual well-being). The BREAST-Q is a validated PRO instrument used to study the impact and effectiveness of breast reconstruction.[17] The Patient Reported Outcomes Measurement Information System (PROMIS-29) subscale for physical functioning, also chosen for analysis, is a self-administered survey developed under the NIH Roadmap for Medical Research for use in a wide range of disease conditions.[19]

Statistical Analysis

Clinical and demographic characteristics across race and ethnicity groups were compared using ANOVA for continuous variables and chi-square tests for categorical variables. For clinical outcomes, any complication, major complication and reconstructive failure at one year postoperatively were each summarized as counts and percentages by race and ethnicity group. Separate mixed-effects logistic regression models were performed, with the dependent variable as the presence or absence of each clinical outcome. The models included race and ethnicity group as the primary predictor, with White (non-Hispanic and non-Latina) as the reference category. The models also included clinical and demographic characteristics as covariates, and random intercepts for centers (hospitals) to account for between-center variability. Adjusted odds ratios (ORs) with 95% confidence intervals (CIs) and *p*-values from the models were reported.

Mean PRO scores at baseline and at one year postoperatively were reported by race and ethnicity group. To further compare one-year PROs across different race and ethnicity groups, separate mixed-effects regression models were employed for each PRO measure. Each model was adjusted for baseline value of the corresponding outcome variable and adjusted for significant clinical and demographic characteristics. The model also included centers (hospitals) as random intercepts to account for between-center variability. To reduce potential bias from differential non-response rates, analyses were weighted by the inverse-of-the-probability-of-response. The probability-of-response was estimated based on data from all eligible study participants (N=2,703), where a separate logistic regression model was fit for each outcome measure, with non-missing response status as the dependent variable and baseline patient characteristics and baseline values of the outcome variable as predictors. All statistical analyses were performed in SAS 9.4 (SAS Institute, Cary, NC).

RESULTS

Baseline Characteristics

The analytic cohort consisted of 2,703 women who underwent autologous or implant-based breast reconstruction, including 2,244 (83.0%) White, 158 (5.9%) Black or African-American, 148 (5.5%) Hispanic or Latina, and 153 (5.7%) patients from other minority groups. A comparison of baseline characteristics demonstrated that Black or African-American women were more likely to have higher BMIs and diabetes, as well as lower levels of education and income than White women (Table 1). However, Black or African-American women were also less likely to be current smokers and more likely to undergo

unilateral procedures than White women. Hispanic and Latina women were younger, less-educated, and reported lower income levels than White women.

Clinical Outcomes

At one-year following breast reconstruction, White and Black or African-American women were more likely to experience a major complication ($P<.001$) or any type of complication (P<.001) relative to Hispanic or Latina and other race and ethnicity group women (Table 2). Reconstructive failures showed similar trends, although the this study is underpowered to detect a true difference in this outcome. In multivariable models, Hispanic or Latina women were less likely to experience a major complication (Adjusted Odds Ratio (OR) = 0.53, $P = .03$) or any complication (OR = 0.52, $P = .008$) than White women (Table 3). Females from other race and ethnicity groups were also less likely to experience a major complication (OR = 0.52, $P = .02$) than White women. There were no other adjusted differences in clinical outcomes based upon race and ethnicity.

Patient Reported Outcomes

Surveys evaluating PROs at one year were completed by 74.0% in White (1,583 of 2,140), 47.6% in Black or African-American (70 of 147), 57.9% in Hispanic or Latina (84 of 145), and 59.5% in other minority groups (88 of 148). Prior to reconstruction, White women reported having better physical functioning, which was reflected by higher BREAST-Q physical well-being scores and PROMIS-29 physical functioning scores. Satisfaction with breast, psychosocial well-being and sexual well-being were similar across race and ethnicity groups before surgery (Table 4). In adjusted models at one year postoperatively, Black or African-American women experienced better psychosocial ($P=.012$) and sexual well-being ($P=.022$) relative to White women (Table 5). There were no racial or ethnic differences noted in satisfaction with breast, physical well-being, and PROMIS-29 physical functioning metrics in adjusted models following breast reconstruction.

DISCUSSION

After adjusting for pertinent clinical and socioeconomic variables, racial and ethnic minorities reported outcomes equivalent to, or by some measures, better than those of White women at one year following breast reconstruction. The psychosocial benefits of breast reconstruction appear to be shared among women who choose to undergo these procedures, regardless of race and ethnicity. These findings provide reassurance in the context of numerous racial and ethnic disparities in health outcomes for women diagnosed with breast cancer.[20–22] Furthermore, these findings build upon our understanding of racial and ethnic variations in the delivery and outcomes of care to women with breast cancer or at risk for developing breast cancer.

Disparities for Black or African-American women are well documented with regard to patient age and stage of cancer at time of diagnosis, as well as cancer aggressiveness and cancer-related mortality.[20–26] Language and psychosocial barriers in access to breast reconstruction following mastectomy have also been characterized for Black or African-American women.[12,14,15] In our study, a higher prevalence of obesity and diabetes was

observed in Black or African-American women, in addition to lower levels of education, income, and self-reported physical functioning prior to breast reconstruction. We also noted that Black or African-American women were less likely to undergo prophylactic mastectomy and bilateral breast reconstruction than White women over the study period.

After adjusting for potential confounding factors, our analysis found that Black or African-American women undergoing breast reconstruction reported better psychosocial and sexual well-being relative to White women. Previous studies have alluded to social and cultural factors, such as expectations for female appearance, which influence a woman's decision to pursue breast reconstruction following mastectomy. [14,27] We hypothesize that these factors may continue to influence PROs postoperatively. An assessment of how social and cultural factors may influence PROs among women undergoing breast reconstruction remains an important area of future research.

An important limitation of this study is that the proportion of women from racial and ethnic minorities who participated in the MROC study is low. This study is not unlike other studies demonstrating that racial and ethnic minorities respond less frequently to follow-up surveys.[28,29] To improve retention among participants, study personnel contacted the participants by e-mail at pre-specified intervals following breast reconstruction to complete PRO surveys. If there was no response, study personnel then attempted to contact participants by telephone and postal mail. Given the availability of e-mail, telephone, or postal mail in contemporary society, it seems unlikely that differential access to these methods of communication can adequately explain the discrepancy. Previous studies on this topic suggest that socioeconomic factors such as lack of flexibility of time, decreased social support, and inability to provide several alternate contacts influence retention of study participants from racial and ethnic minority groups.[29,30]

In conjunction with the commencement of President Obama's Precision Medicine initiative, there has been nationwide focus on recruitment and retention of racial and ethnic minority populations in clinical and biomedical research to improve internal and external validity of study findings.[31] Strategies to increase recruitment and retention of underrepresented minority groups in clinical research have been studied primarily in the context of randomized controlled trials and census-based research. Studies suggest that recruitment of racial and ethnic minorities may be improved by aggressive outreach, utilization of patient navigators, and improved communication between patients and providers.[32–35] Retention of study participants may be improved by employing an array of approaches to follow-up by study personnel, including persistence of initiating contact, promotion of perceived benefits to self and others, financial incentives, minimizing the overall burden of paperwork, identifying multiple contact numbers, and recognizing and addressing possible barriers to follow-up early in study enrollment.[29,30,36]

Our results suggest that Hispanic or Latina women experienced fewer clinical complications following reconstruction. These findings are notable in the context of a rapidly growing population of Hispanic and Latina women in the United States. Interestingly, a similar association was shown in a previous study using the American College of Surgeons-National Surgical Quality Improvement data sets.[37] Although the prevalence of comorbidities was

similar, Hispanic or Latina women were noted to have lower levels of education, income, and self-reported physical well-being than White women. This association seems consistent with well-documented, paradoxically improved health outcomes among Hispanics and Latinas relative to White individuals despite lower levels of income and education.[38] Proposed explanations for these findings have included the unanticipated selection of healthier Hispanic and Latina women through the process of immigration, as well as stronger social and cultural support networks for these individuals.[38] It is also possible that our findings for this population are due, in part, to selection bias through offering breast reconstruction to healthier Hispanic or Latina women.

This study utilized a multi-institutional, prospective cohort design that included all common forms of breast reconstruction following mastectomy with one year of follow-up data. Previous studies on this topic have been limited by procedure type, length of follow-up, and lack of validated PRO measures.[37,39] Additionally, patients undergoing prophylactic mastectomy followed by breast reconstruction were included in our analysis, reflecting an increasingly common trend, and thus improving the generalizability of our findings.[40] Notable limitations include the relatively small sample of racial and ethnic minority patients who participated in the MROC Study. As a result, a third category of ‘other’ was created for analytic purposes and consisted of multiple racial and ethnic groups, limiting analysis of any one of these groups individually. As always is the case with observational data, it is also possible that the adjusted models did not control for all potential confounding factors, known and unknown. Furthermore, most sites involved in the MROC study were based in large academic centers, and as such, their results may not be generalizable to patients treated in smaller practice settings.

CONCLUSION

Despite a growing body of literature identifying disparities in breast cancer outcomes, racial and ethnic minorities undergoing post-mastectomy breast reconstruction experienced outcomes equivalent to or better than those of White women. Interestingly, the data suggest that Black or African-American women reported a greater increase in psychosocial and sexual well-being, and Hispanic or Latina women experienced fewer clinical complications than White women. Future studies assessing PROs following breast reconstruction should aim to improve recruitment and loss to follow-up among underserved populations to improve validity and generalizability of study findings.

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Abbreviations

MROC Mastectomy Reconstruction Outcomes Consortium

PRO	Patient Reported Outcome
PROMIS	Patient-Reported Outcomes Measurement Information System
BMI	Body Mass Index
OR	Odds ratio
CI	Confidence Interval

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SUMMARY

Using prospective data collected from a network of 11 leading medical centers, we aimed to identify and assess racial and ethnic variations in clinical and patient-reported outcomes at one-year following breast reconstruction. In multivariable models, Hispanic women were less likely to experience clinical complications than White women and Black women experienced improved psychosocial and sexual well-being relative to White women following breast reconstruction.

Table 1

Baseline sociodemographic and clinical characteristics of the analytic cohort

Characteristic	White n (%)(n=2,244)	Black or African- American n (%)(n=158)	Hispanic or Latina n (%)(n=148)	Other* n (%)(n=153)	*P*-Value†
Age, mean (SD)	49.9 (10.2)	49.7 (10.5)	45.5 (8.9)	47.6 (9.2)	<.001
BMI, mean (SD)	26.5 (5.6)	30.6 (6.5)	27 (5.5)	25.7 (4.8)	<.001
Education					.003
No college	585 (26.2)	57 (36.3)	50 (33.8)	32 (21.2)	
College	1,651 (73.8)	100 (63.7)	98 (66.2)	119 (78.8)	
Household annual income					<.001
<$50,000	340 (15.7)	65 (41.4)	35 (24.7)	28 (19.1)	
$50,000–$99,999	699 (32.2)	51 (32.5)	62 (43.6)	49 (33.3)	
>$100,000	1,133 (52.1)	41 (26.1)	45 (31.7)	70 (47.6)	
Smoking					.003
Non-smoker	1,403 (63.1)	113 (71.5)	113 (76.9)	107 (71.8)	
Previous smoker	761 (34.3)	42 (26.6)	31 (21.1)	37 (24.8)	
Current smoker	58 (2.6)	3 (1.9)	3 (2.0)	5 (3.4)	
Procedure type					.199
Implant-based	1,522 (67.8)	113 (71.5)	108 (73.0)	90 (58.8)	
Autologous	659 (29.4)	41 (26.0)	36 (24.3)	57 (37.3)	
Latissimus Dorsi	63 (2.8)	4 (2.5)	4 (2.7)	6 (3.9)	
Laterality					<.001
Unilateral	949 (42.3)	93 (58.9)	71 (48.0)	82 (53.6)	
Bilateral	1,295 (57.7)	65 (41.1)	77 (52.0)	71 (46.4)	
Timing					
Immediate	2056 (91.6%)	143 (90.5%)	131 (88.5%)	142 (92.8%)	0.162
Delayed	146 (6.5%)	12 (7.6%)	15 (10.1%)	5 (3.3%)	
Mixed	42 (1.9%)	3 (1.9%)	2 (1.4%)	6 (3.9%)	
Indication for mastectomy					.047
Therapeutic	1,983 (88.4)	147 (93)	136 (91.8)	143 (93.4)	
Prophylactic	261 (11.6)	11 (7.0)	12 (8.1)	10 (6.5)	
Diabetes Mellitus	73 (3.3)	14 (8.9)	6 (4.1)	20 (13.1)	<.001

Characteristic	White n (%)(n=2,244)	Black or African- American n (%)(n=158)	Hispanic or Latina n (%)(n=148)	Other* n (%)(n=153)	*P*-Value†
Radiation					.909
Before reconstruction	296 (13.2)	24 (15.2)	21 (14.2)	16 (10.5)	
After reconstruction	421 (18.8)	26 (16.5)	27 (18.2)	28 (18.3)	
None	1,527 (68.0)	108 (68.3)	100 (67.6)	109 (71.2)	

Standard deviation, SD; Body mass index, BMI;

Cases with missing information are excluded. Given in absolute numbers (n) and as percentage of patients in that characteristic group.

*Other category includes Asian, Native American/Alaska Native, Native Hawaiian, or other Pacific Islander

†X^2 for categorical variables, *t* test for continuous variables

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Table 2

Unadjusted one-year complication rate following breast reconstruction by self-reported race and ethnicity

Variable	Number of patients	Any complication n (%)(*P* <.001)	Major complication n (%)(*P*<.001)	Reconstruction failure n (%)(*P*=.179)
White	2,244	746 (33.2)	503 (22.4)	104 (4.6)
Black or African-American	158	45 (28.5)	33 (20.9)	11 (7.0)
Hispanic or Latina	148	25 (16.9)	18 (12.2)	3 (2.0)
Other*	153	42 (27.5)	18 (11.8)	5 (3.3)

Cases with missing information are excluded. Given in absolute numbers (n) and as percentage of patients in that characteristic group.

*Other category includes Asian, Native American//Alaska Native, Native Hawaiian, or other Pacific Islander

Table 3

Multivariable logistic regression models predicting one-year clinical outcomes following breast reconstruction by self-reported race and ethnicity

	Any complication			Major complication			Reconstruction failure		
Variable	**OR**	**95% CI**	***P*-Value**	**OR**	**95% CI**	***P*-Value**	**OR**	**95% CI**	***P*-Value**
White	Reference			Reference			Reference		
Black or African-American	0.80	0.53–1.19	.261	0.80	0.51–1.25	.325	0.95	0.46–1.95	.885
Hispanic or Latina	0.52	0.32–0.84	.008	0.53	0.30–0.94	.028	0.41	0.12–1.35	.143
Other *	0.78	0.51–1.18	.234	0.52	0.30–0.89	.018	0.76	0.27–2.17	.613

OR, odds ratio; CI, confidence interval

Adjusted for age, body mass index, annual household income, education, smoking status, procedure type, laterality of reconstruction, prophylactic mastectomy, diabetes, radiation therapy

* Other category includes Asian, Native American//Alaska Native, Native Hawaiian, or other Pacific Islander

Table 4

Unadjusted one-year patient reported outcomes following breast reconstruction by self-reported race and ethnicity

Characteristic	Time	White	Black or African- American	Hispanic or Latina	Other*
BreastQ – Satisfaction with breast	Baseline	60 (21.9)	59.3 (25.3)	60.2 (24.3)	60.2 (22.1)
	One year	64.7 (17.8)	61.7 (19.8)	65.4 (19.4)	64.5 (16)
BreastQ - Psychosocial well-being	Baseline	69.4 (17.9)	69.6 (20.8)	70.1 (20.8)	68.3 (18)
	One year	72.6 (19.1)	74.9 (23)	71.8 (22.1)	72.3 (19.1)
BreastQ - Physical well-being	Baseline	79.7 (14.5)	76.8 (14.9)	75.5 (16.8)	74.1 (15.6)
	One year	75.8 (14.6)	75.1 (16.3)	76.2 (15.1)	71.6 (15)
BreastQ - Sexual well-being	Baseline	55.2 (20.5)	52.7 (25.2)	56.2 (21.7)	55.9 (18.8)
	One year	53.3 (21.2)	56.8 (23.7)	55 (24.4)	55.2 (19.5)
PROMIS - Physical functioning	Baseline	53.1 (6.6)	50.4 (8.8)	51.7 (7.6)	51.1 (7.6)
	One year	51.4 (7.1)	50 (8.6)	51.6 (6.9)	49.6 (7.5)

Patient-reported outcomes presented as the mean (standard deviation) for each race and ethnicity category

Cases with missing information are excluded. Given in absolute numbers (n) and as percentage of patients in that characteristic group.

*Other category includes Asian, Native American//Alaska Native, Native Hawaiian, or other Pacific Islander

Table 5

Multivariable mixed effects regression models predicting one-year clinical outcomes following breast reconstruction by self-reported race and ethnicity

	Satisfaction with Breast			Psychosocial well-being			Physical well-being			Sexual well-being			PROMIS physical functioning		
Variable	**β**	**95% CI**	***P*- Value**	**β**	**95% CI**	***P*- Value**	**β**	**95% CI**	***P*- Value**	**β**	**95% CI**	***P*- Value**	**β**	**95% CI**	***P*- Value**
White		Reference			Reference			Reference			Reference			Reference	
Black or African- American	0.16	−.45–3.76	.933	4.71	1.05–8.36	.012	1.39	−.43–4.21	.335	5.00	0.71–9.28	.022	−.11	−.42–1.20	.870
Hispanic or Latina	1.42	−.19–5.02	.441	−.62	−.30–3.06	.742	2.03	−.80–4.86	.159	1.07	−.12–5.25	.618	0.31	−.00–1.62	.641
Other *	−.69	−.26–2.87	.704	−.03	−.64–3.59	.989	−.98	−.78–0.82	.166	1.07	−.10–5.25	.614	−.67	−.98–0.63	.313

CI, confidence interval

Adjusted for baseline patient-reported outcome value, age, body mass index, annual household income, education, procedure type, laterality of reconstruction, prophylactic mastectomy, diabetes, radiation therapy.

Weighted by the non-response rates

* Other category includes Asian, American-Indian Native American/Alaska Native, Native Hawaiian, or other Pacific Islander