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Non-response Bias in Survey Research: Lessons from a Prospective Study of Breast Reconstruction

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STRUCTURED ABSTRACT

Introduction—Survey-based research is essential for evaluating the outcomes of health care in an era of patient centered care. However, many such studies are hampered by poor response rates in completion of study questionnaires, thus limiting the generalizability of any findings. The objectives of this analysis were to identify independent variables associated with non-response to surveys following breast reconstruction to improve future patient-reported outcomes research.

Materials and Methods—The Mastectomy Reconstruction Outcomes Consortium is a prospective cohort study involving 11 leading medical centers from the United States and Canada. Non-response rates for surveys assessing satisfaction with breast, satisfaction with care (BREAST-Q), depression (PHQ-9), and anxiety (GAD-7) were measured at one year and two years postoperatively. Clinical complication rates were compared between responders and non-responders, and multivariable models were used to assess predictors of non-response.

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Acquisition, analysis, or interpretation of data: Berlin, Hamill, Qi, Kim, Pusic, Wilkins

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Results—Among 2,856 women in the analytic cohort, 1,882 (65.9%) underwent implant-based, 817 (28.6%) received autologous, and 157 (5.5%) underwent latissimus dorsi myocutaneous flap breast reconstructions. Non-response rates to surveys at one year and two years were 27.8% and 34.4% respectively. Race and ethnicity and annual household income were associated with non-response to surveys. Women who underwent implant-based procedures were less likely to complete long-term surveys.

Conclusions—As survey-based research plays an increasingly prominent role in evaluating the outcomes of breast reconstruction, we found socioeconomic and procedure-related differences in survey response rates. Investigators must consider systematic differences in response rates among particular groups of women on the generalizability and validity of findings and perform rigorous non-response bias analyses.

Keywords

Patient reported outcomes; surgical outcomes; breast cancer; breast reconstruction; epidemiology; study bias

INTRODUCTION

Advances in the measurement of patient-reported outcomes (PROs) have enabled surgeons and health services researchers to investigate improvements in health related quality of life related to surgical care. Furthermore, as comparative effectiveness research becomes increasingly prominent in nearly all areas of surgery, survey-based research methods are also frequently used to compare the impact of different surgical procedures. As we move forward in this era of patient centered care, it has become increasingly clear that survey-based research is an essential component of assessing the impact of surgical procedures.

The American Cancer Society estimates that breast cancer is the most common non-skin cancer among women in the United States.¹ Although breast conservation remains the primary surgical treatment for breast cancer, mastectomy is still performed on a routine basis.²⁻⁵ To decrease the adverse effects of mastectomy on psychosocial functioning, many women undergo breast reconstruction following mastectomy. According to the American Society for Plastic Surgeons, approximately 109,256 women underwent breast reconstruction following mastectomy in the United States in 2016.⁶ Building on recent advances in survey-based research, surgeons and health services researchers commonly use validated PRO instruments to evaluate health-related quality of life and psychosocial functioning among women undergoing breast reconstruction following mastectomy.⁷⁻¹²

In contrast to medical records or claims data, measuring PROs is entirely dependent on the patients' willingness to complete surveys. Importantly, systematic differences between patients who respond to surveys and those who do not respond may lead to non-response bias, which as a form of measurement bias threatens the generalizability and validity of study findings. Although PRO measures have been increasingly applied in breast reconstruction and other areas of surgery, few authors have assessed or adequately adjusted for non-response bias in study findings.

Investigators should not assume that non-response to surveys occurs randomly. Patient willingness to complete postoperative surveys may be affected by patient, clinical, or procedure-related differences. To assess patient outcomes in a rigorous manner, investigators should perform non-response bias analyses. Using data collected in a multi-institutional, prospective cohort study of breast reconstruction, our objective in the current analysis was to identify sociodemographic, clinical, and procedural characteristic associated with not completing postoperative surveys. In this article, we also discuss approaches to assessing and adjusting for non-response bias for PRO surveys in this study population.

PATIENTS AND METHODS

Data Source and Analytic Cohort

The Mastectomy Reconstruction Outcomes Consortium Study is a five-year NCI-funded longitudinal, prospective cohort study assessing clinical and patient reported outcomes of breast reconstruction following mastectomy. This study enrolled eligible patients at 11 participating centers in the U.S. and Canada between February 2012 and July 2015. Institutional approval was obtained at all participating institutions and informed consent was obtained from all women who participated in the study. Women undergoing immediate or delayed reconstructive procedures, unilateral or bilateral reconstruction, prophylactic or therapeutic mastectomy, and one of eight commonly used methods of breast reconstruction were eligible for recruitment into the study. The eleven centers of the consortium encompassed urban, rural, academic, and private practice settings. Data were predominantly collected through web-based structured surveys and reviews of medical records. Research protocols were developed and reviewed with study personnel to promote retention of study participants. If study participants failed to complete postoperative surveys, personnel attempted to contact the participants by email, telephone and/or mail. If requested, paper versions of the questionnaires were mailed to study participants. No monetary incentives were offered to encourage patient participation in this study.

Potential Predictors of Non-response

Baseline socioeconomic information, including race, ethnicity, age, highest level of education attained, and annual household income were collected by structured web-based surveys in the preoperative period. Clinical information, including surgery date, histologic diagnosis, date and sides of mastectomy, date and type of radiation therapy, body mass index, smoking status, and medical comorbidities were collected from electronic medical records. Breast reconstruction procedures were categorized as implant-based, latissimus dorsi myocutaneous flap, and autologous reconstructions. Autologous breast reconstruction included all methods of abdominally-based breast reconstruction (free tissue transfer and pedicled myocutaneous flaps) as well as superior and inferior gluteal artery perforator flap procedures. One-year and two-year clinical complication rates were compared between survey responders and non-responders. Variations in non-response rates at one year were compared to overall patient satisfaction with postoperative care at three months. The effect of study site on likelihood of non-response to surveys was also assessed in multivariable models.

Non-response to Survey Instruments

The PRO measures chosen to evaluate non-response to survey instruments included the BREAST-Q Survey for satisfaction with breast and with care, the Patient Health Questionnaire (PHQ) for symptoms of depression, and the Generalized Anxiety Disorder Survey (GAD). All survey instruments have been validated and are commonly employed to study the patient-reported benefits of breast reconstruction.^{13–15} The primary outcome of interest, non-response to surveys, was defined as non-response for all subscales of either the BREAST-Q or PHQ/GAD questionnaires at pre-specified postoperative time points. Furthermore, if answers were so limited that the surveys could not be scored for measurement of PROs, this outcome was categorized as non-response. Non-response to survey instruments was assessed at one year and two years following breast reconstruction.

Statistical Analysis

Baseline clinical and demographic characteristics were compared between responders and non-responders using t-tests for continuous variables and chi-square tests for categorical variables. Separate multivariable logistic regression models were used with non-response at each assessment time as the dependent variable. Final models included independent variables selected using a stepwise approach, with criteria for inclusion set *a priori* at $p < 0.15$. Adjusted odds ratios (ORs) with 95% confidence intervals (CIs) and p -values from the models were reported. All statistical analyses were performed in SAS 9.4 (SAS Institute, Cary, NC).

RESULTS

Among 2,856 women enrolled in the Mastectomy Reconstruction Outcomes Consortium Study, 1,882 (65.9%) underwent implant-based, 817 (28.6%) received autologous, and 157 (5.5%) underwent latissimus dorsi myocutaneous flap breast reconstruction. Non-response rates to BREAST-Q surveys at one and two years postoperatively were 27.8% and 34.4%, respectively (Table 1). Non-response rates to PHQ/GAD surveys at one and two years postoperatively were 29.3% and 36.4%, respectively (data not shown). At one year following reconstruction, the rate of non-response ranged from 8.0% to 41.4% among participating centers.

Racial and ethnic minorities and women with lower annual household incomes were more likely to be non-responders to the BREAST-Q and PHQ/GAD surveys (Table 1). Non-responders to surveys at one and two years were less likely to be married or in a relationship. Women who underwent implant-based breast reconstruction were less likely to respond to the BREAST-Q and PHQ/GAD surveys at one and two years postoperatively. Women with bilateral procedures were less likely to complete the PHQ/GAD surveys at one and two years. There were no associations between measures of patient satisfaction with information, surgeon, medical team, or office staff assessed at three months and non-response to surveys at one year (Table 2). Incidences of major clinical complications (27.0% vs. 27.9%, $p=0.71$) or any clinical complication (26.5% vs. 28.3%, $p=0.36$) at one year were not associated with non-response to surveys at one year. Furthermore, incidences of major clinical complications

(31.8% vs. 35.5%, $p=0.99$) or any clinical complication (30.4% vs. 35.3%, $p=0.06$) at two years were not associated with non-response to surveys at two years.

In multivariable models, race and ethnicity and annual household income were independently associated with non-response to BREAST-Q and PHQ/GAD surveys at one and two years postoperatively (Tables 3 and 4). Furthermore, women undergoing implant-based breast reconstruction were more likely to not complete BREAST-Q and PHQ/GAD surveys at two years when compared to women who underwent autologous reconstruction (OR 1.50, 95% CI 1.10–2.05, $p=.01$ and OR 1.41, 95% CI 1.04–1.91, $p=.03$, respectively). Women who underwent bilateral reconstruction were less likely to respond to PHQ/GAD surveys at one year when compared with women who underwent unilateral reconstruction (OR 1.24, 95% CI 1.02–1.52, $p=.03$). Furthermore, current smokers at the time of their initial operation were less likely to complete BREAST-Q and PHQ/GAD surveys at two years (OR 2.02, 95% CI 1.02–3.97, $p=.04$ and OR 2.01, 95% CI 1.02–3.97, $p=.04$, respectively). There were no meaningful differences noted between models predicting non-response to BREAST-Q and PHQ-GAD surveys.

DISCUSSION

Non-response bias is an ongoing concern for investigators in survey-based research, since not all study participants will complete postoperative surveys. Using data collected from the Mastectomy Reconstruction Outcomes Consortium, we demonstrate that nonresponse to surveys did not occur randomly among women who underwent breast reconstruction. We found important socioeconomic effects on survey response rates that allude to an incomplete understanding of previously reported disparities in the breast reconstruction outcomes across these variables. Furthermore, women who underwent implant-based or bilateral procedures were less likely to complete long-term surveys. As survey-based research continues to play an instrumental role in the evaluation of surgical procedures, investigators must consider the impact of systematic differences in response rates among particular groups of patients on the interpretation, generalizability, and validity of study findings.

Despite federally mandated insurance coverage in the United States for breast reconstruction following mastectomy, studies have shown racial and ethnic disparities in access to these procedures.^{16–22} In our study, we found important socioeconomic effects on survey response rates following breast reconstruction. These findings highlight potential limitations of existing and ongoing research on socioeconomic disparities in patient reported outcomes following breast reconstruction. In addition to selection bias that may exist due to disparities in access to these procedures, our data demonstrate notable non-response biases when assessing survey outcomes in these groups. Qualitative follow-up studies are needed to identify the underlying causes of differences in response rates, to improve the design of future studies assessing socioeconomic disparities in patient reported outcomes following breast reconstruction.

Implant-based procedures are the most commonly performed methods of breast reconstruction in the United States.^{4,23} Women who underwent these procedures in our study were less likely to complete surveys at two years postoperatively than those who

receiving autologous procedures. As PROs are increasingly used in comparative effectiveness research, investigators will need to consider and adjust for non-response bias in studies comparing long-term survey-based outcomes between different breast reconstruction procedures. The etiology for procedure-related differences in response rates is unclear. The discomfort from serial expansions should have resolved by two-years, given that the vast majority of women had already undergone exchange for permanent implants. It remains possible that the observed discrepancy in response rates may be due to differences in commitment to participating in breast reconstruction research in this population.

The wide range of non-response rates (8.0% to 41.4%) at one year among the eleven participating centers in the Mastectomy Reconstruction Outcomes Consortium is not unexpected. Notably, patient satisfaction with surgeon, medical team, and office staff at the site level did not correlate with survey completion. We believe that variations in non-response rates at the site level were due to underlying differences in site coordinators' expertise and patient-related differences in travel distance to the treating hospital. To reduce potential differences in follow-up rates at the site level in multi-institutional studies, it is important that research protocols are developed to promote retention of study participants and standard operating procedures for patient follow-up are repeatedly reviewed with study personnel for consistency across sites in data collection. Furthermore, adjusting for the effect of site-specific differences in PRO analyses for multi-institutional studies should be performed in future prospective studies.

Survey response rates are often used as an important criterion for assessing quality of survey-based research studies. However, previous investigators have noted that an over-emphasis on minimizing non-response rates may be counterproductive.^{24–26} Some authors have suggested that undue focus on achieving high response rates may result in misallocation of funds that could have been better used to increase sample size and collecting information to enable nonresponse bias analyses.²⁴ To adjust for non-response bias in survey research, there have been many approaches described in the literature.²⁵ It is possible to weight responses by the inverse of the probability of response or perform multiple imputation techniques.^{27–29} Importantly however, these approaches assume that the likelihood of non-response is not associated with the unobserved responses after having considered the observed sociodemographic and clinical characteristics of participants. If there is a high suspicion that unmeasured characteristics are associated with non-response, then it is recommended that index function models be applied in statistical analyses.²⁷

Although we included socioeconomic, clinical, and PRO data from a multi-institutional prospective study, there are limitations that should be considered. Importantly, we were unable to perform follow-up interviews with women who did not complete surveys, to better characterize the specific reasons for non-response. Furthermore, most sites involved in the Mastectomy Reconstruction Outcomes Consortium were large academic centers. Thus, study findings may not be generalizable to smaller or private practice settings.

CONCLUSION

In this era of patient-centered care and precision medicine initiatives, rigorous qualitative and quantitative studies will build upon our current understanding of the impact of surgical procedures. As survey-based research continues to play an increasingly prominent role in breast reconstruction and other areas of surgery, our study demonstrates important socioeconomic disparities and procedure-related differences in survey response rates. Investigators assessing PROs following breast reconstruction should perform non-response bias analyses and consider the implications of systematic differences in response rates among particular groups of patients on study findings.

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Abbreviations

OR	Odds Ratio
CI	Confidence Interval
PROs	Patient Reported Outcomes

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Table 1

Non-response to BREAST-Q surveys by baseline socioeconomic and clinical characteristic

	One year post-op n (%) (n=2,856)		Two years post-op n (%) (n=2,211)	
Characteristic	Non-response 793 (27.8%)	P-value	Non-response 760 (34.4%)	P-value
Race		<.001		<.001
White	643 (25.7%)		630 (32.4%)	
Black	85 (48.0%)		74 (54.0%)	
Other *	63 (37.5%)		52 (42.3%)	
Ethnicity		<.001		<.001
Hispanic or Latino	68 (41.2%)		64 (49.2%)	
Non-Hispanic or Latino	725 (27.0%)		696 (33.5%)	
Annual household income		.001		.007
<\$50,000	166 (33.7%)		165 (41.5%)	
\$50,000–\$99,999	266 (29.2%)		235 (33.0%)	
>\$100,000	345 (25.2%)		341 (33.1%)	
Education		.006		.479
High school or less	83 (28.1%)		87 (37.5%)	
Some college	162 (34.2%)		126 (34.6%)	
College degree	321 (26.1%)		328 (34.7%)	
Master/doctoral degree	224 (26.5%)		213 (32.2%)	
Marital Status		.004		.005
Married or partnered	583 (26.4%)		560 (32.7%)	
Not married or partnered	201 (32.2%)		192 (39.6%)	
Employment status		.090		.113
Full-time	467 (28.4%)		439 (34.9%)	
Part-time	81 (22.8%)		81 (28.8%)	
Unemployed	233 (28.4%)		230 (35.5%)	
Age (mean, SD)	48.8 (9.9)	.034	47.9 (10.2)	<.001
BMI (mean, SD)	27.6 (6.1)	<.001	27.2 (6.1)	.007
Procedure type		<.001		<.001
Implant-based	584 (31.0%)		550 (38.7%)	
Autologous	173 (21.2%)		165 (24.8%)	
Latissimus Dorsi	36 (22.9%)		45 (35.7%)	
Laterality		.057		.028
Unilateral	325 (26.0%)		307 (31.8%)	
Bilateral	468 (29.2%)		453 (36.3%)	
Indication		.258		.678
Breast cancer	718 (28.1%)		683 (34.2%)	

	One year post-op n (%) (n=2,856)		Two years post-op n (%) (n=2,211)	
Characteristic	Non-response 793 (27.8%)	P-value	Non-response 760 (34.4%)	P-value
Prophylactic	75 (25.0%)		77 (35.6%)	
Timing		.694		.925
Immediate	721 (27.9%)		689 (34.4%)	
Delayed	49 (25.4%)		51 (33.1%)	
Mixed	23 (29.9%)		20 (35.7%)	
Diabetes Mellitus		.933		.946
Yes	34 (28.1%)		34 (34.7%)	
No	759 (27.8%)		726 (34.4%)	
Smoking status		.222		.037
Non-smoker	497 (26.8%)		470 (32.9%)	
Previous smoker	266 (29.1%)		260 (36.2%)	
Current smoker	22 (34.4%)		22 (48.9%)	
Radiation		.857		.733
Before	115 (27.5%)		112 (35.7%)	
During and/or after	143 (26.9%)		143 (35.4%)	
None	535 (28.1%)		505 (33.8%)	
Chemo		.390		.252
During or after	237 (28.9%)		233 (36.2%)	
No chemo during or after	556 (27.3%)		527 (33.6%)	

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.

Statistical tests included χ^2 for categorical variables, *t* test for continuous variables.

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

Table 2

Association between satisfaction with care and non-response to patient reported outcome measures at one year postoperatively

Variable	Non-respondent to BREAST-Q (mean, SD)	Respondent to BREAST-Q (mean, SD)	P-value *
Satisfaction with information	72.8 (19.1)	73.2 (17.4)	.665
Satisfaction with surgeon	89.4 (16.2)	90.1 (15.3)	.378
Satisfaction with medical team	93.6 (14.9)	92.4 (16.4)	.173
Satisfaction with office staff	95.7 (11.9)	95.8 (11.5)	.911
	Non-respondent to PHQ/GAD	Respondent to PHQ/GAD	
Satisfaction with information	72.6 (19.0)	73.3 (17.4)	.435
Satisfaction with surgeon	89.2 (16.5)	90.2 (15.2)	.230
Satisfaction with medical team	93.2 (15.4)	92.5 (16.3)	.387
Satisfaction with office staff	95.4 (12.5)	95.9 (11.3)	.471

Satisfaction surveys sent to patients at 3 months postoperatively.

*
t test for continuous variables

Table 3

Multivariable logistic regression models predicting non-response to BREAST-Q surveys at one year and two years postoperatively

Variable	Non-response at one year			Non-response at two years		
	OR	95% CI	P-Value	OR	95% CI	P-Value
Age (β value reported)	0.99	0.98–1.00	.127	0.98	0.97–0.99	<.001
BMI (β value reported)	1.04	1.03–1.06	<.001	1.04	1.02–1.06	<.001
Race						
White		Reference			Reference	
Black or African-American	1.86	1.31–2.65	.001	1.82	1.21–2.75	.004
Other*	2.08	1.43–3.03	<.001	1.64	1.06–2.55	.027
Ethnicity						
Non-Hispanic or Latino		Reference			Reference	
Hispanic or Latino	1.58	1.10–2.28	.014	1.63	1.06–2.50	.026
Education						
Master/doctoral degree		Reference			Reference	
High school or less	1.34	0.93–1.93	.122	1.73	1.15–2.60	.008
Some college	1.57	1.17–2.09	.003	1.29	0.93–1.81	.129
College degree	1.01	0.81–1.25	.959	1.36	1.06–1.74	.015
Annual household income						
>\$100,000		Reference			Reference	
<\$50,000	1.39	1.03–1.86	.031	1.46	1.06–2.02	.022
\$50,000–\$99,999	1.20	0.97–1.50	.100	1.01	0.79–1.29	.956
Employment status						
Full-time		Reference			Reference	
Part-time	0.92	0.74–1.14	.422	0.91	0.71–1.15	.427
Unemployed	0.72	0.53–1.00	.047	0.66	0.47–0.93	.019
Marital status						
Married or partnered		Reference			Reference	
Not married or partnered	1.15	0.91–1.45	.244	1.23	0.95–1.59	.122
Procedure type						

Variable	Non-response at one year			Non-response at two years		
	OR	95% CI	P-Value	OR	95% CI	P-Value
Autologous		Reference			Reference	
Implant-based	1.24	0.94–1.64	.120	1.50	1.10–2.05	.010
Latissimus Dorsi	0.68	0.42–1.10	.115	1.24	0.74–2.07	.409
Timing of reconstruction						
Immediate		Reference			Reference	
Delayed	0.86	0.54–1.35	.502	1.16	0.71–1.88	.559
Mixed	1.24	0.67–2.27	.497	1.22	0.60–2.45	.584
Lymph node biopsy						
None		Reference			Reference	
Sentinel lymph node biopsy	0.96	0.71–1.29	.773	1.11	0.79–1.56	.529
Axillary lymph node dissection	0.91	0.65–1.29	.607	1.19	0.81–1.75	.375
Indication						
Therapeutic		Reference			Reference	
Prophylactic	0.95	0.66–1.37	.782	1.37	0.91–2.08	.135
Laterality						
Unilateral		Reference			Reference	
Bilateral	1.21	0.99–1.48	.064	1.09	0.87–1.36	.466
Smoking status						
Non-smoker		Reference			Reference	
Previous smoker	1.12	0.91–1.37	.277	1.21	0.97–1.51	.096
Current smoker	1.28	0.71–2.32	.416	2.02	1.02–3.97	.042
Diabetes						
No		Reference			Reference	
Yes	1.00	0.62–1.60	.997	1.12	0.68–1.85	.656
Radiation						
None		Reference			Reference	
Before reconstruction	1.10	0.82–1.48	.510	1.40	1.00–1.95	.050
After reconstruction	1.01	0.76–1.35	.921	1.19	0.86–1.64	.297

Variable	Non-response at one year			Non-response at two years		
	OR	95% CI	P-Value	OR	95% CI	P-Value
Chemotherapy						
None		Reference			Reference	
Before/during reconstruction	1.11	0.89–1.39	.369	1.01	0.78–1.29	.968
Major complication within year one						
No		Reference		-	-	-
Yes	1.10	0.86–1.42	.451	-	-	-
Major complication within two years						
No	-	-	-		Reference	
Yes	-	-	-	0.95	0.72–1.25	.690

OR, odds ratio; CI, confidence interval

Adjusted for site-specific differences

Multivariable logistic regression models predicting non-response to PHQ/GAD surveys at one year and two years postoperatively

Table 4

Variable	Non-response at one year			Non-response at two years		
	OR	95% CI	P-Value	OR	95% CI	P-Value
Age (β value reported)	0.99	0.98–1.00	.081	0.98	0.97–0.99	<.001
BMI (β value reported)	1.05	1.03–1.07	<.001	1.04	1.02–1.06	<.001
Race						
White		Reference			Reference	
Black or African-American	1.84	1.30–2.62	.001	1.67	1.11–2.52	.015
Other*	2.05	1.41–2.98	<.001	1.79	1.16–2.77	.008
Ethnicity						
Non-Hispanic or Latino		Reference			Reference	
Hispanic or Latino	1.52	1.06–2.19	.024	1.39	0.91–2.12	.133
Education						
Master/doctoral degree		Reference			Reference	
High school or less	1.33	0.92–1.91	.124	1.67	1.12–2.50	.012
Some college	1.68	1.26–2.24	<.001	1.34	0.97–1.86	.076
College degree	1.04	0.84–1.29	.713	1.33	1.04–1.69	.021
Annual household income						
>\$100,000		Reference			Reference	
<\$50,000	1.31	0.98–1.75	.072	1.51	1.10–2.08	.012
\$50,000–\$99,999	1.20	0.97–1.50	.095	1.02	0.80–1.30	.886
Employment status						
Unemployed		Reference			Reference	
Full-time (including students)	0.94	0.76–1.17	.594	0.92	0.73–1.17	.501
Part-time	0.77	0.56–1.05	.100	0.62	0.44–0.88	.007
Marital Status						
Married or partnered		Reference			Reference	
Not married or partnered	1.08	0.85–1.36	.538	1.25	0.97–1.61	.090
Procedure type						

Variable	Non-response at one year			Non-response at two years		
	OR	95% CI	P-Value	OR	95% CI	P-Value
Autologous		Reference			Reference	
Implant-based	1.29	0.98–1.69	.066	1.41	1.04–1.91	.025
Latissimus Dorsi	0.79	0.49–1.26	.324	1.13	0.68–1.86	.639
Timing of reconstruction						
Immediate		Reference			Reference	
Delayed	1.10	0.71–1.70	.680	1.09	0.68–1.77	.712
Mixed	1.16	0.63–2.14	.626	1.04	0.52–2.09	.910
Lymph node biopsy						
None		Reference			Reference	
Sentinel lymph node biopsy	1.10	0.71–1.70	.680	1.04	0.74–1.45	.827
Axillary lymph node dissection	1.16	0.63–2.14	.626	1.12	0.77–1.64	.548
Indication						
Therapeutic		Reference			Reference	
Prophylactic	1.00	0.69–1.44	1.000	1.32	0.88–1.99	.180
Laterality						
Unilateral		Reference			Reference	
Bilateral	1.24	1.02, 1.52	.032	1.09	0.87–1.36	.444
Smoking status						
Non-smoker		Reference			Reference	
Previous smoker	1.18	0.97–1.44	.100	1.19	0.95–1.48	.130
Current smoker	1.46	0.81–2.62	.204	2.01	1.02–3.97	.043
Diabetes						
No		Reference			Reference	
Yes	1.02	0.64–1.61	.946	1.05	0.64–1.72	.854
Radiation						
None		Reference			Reference	
Before reconstruction	1.07	0.80–1.43	.659	1.35	0.97–1.88	.072
After reconstruction	1.08	0.81–1.43	.606	1.28	0.93–1.77	.125

Variable	Non-response at one year			Non-response at two years		
	OR	95% CI	P-Value	OR	95% CI	P-Value
Chemotherapy						
None		Reference			Reference	
Before/during reconstruction	1.15	0.92–1.43	.221	0.96	0.75–1.23	.755
Major complication within year one						
No		Reference		-	-	-
Yes	1.10	0.85–1.41	.463	-	-	-
Major complication within two years						
No	-	-	-		Reference	
Yes	-	-	-	0.97	0.74–1.28	.851

OR, odds ratio; CI, confidence interval

Adjusted for site-specific differences