



Published in final edited form as:

J Surg Oncol. 2013 September ; 108(3): 163–168. doi:10.1002/jso.23365.

Trends in Post-mastectomy Reconstruction: A SEER Database Analysis

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Abstract

Background and Objectives—This study was performed to investigate recent trends and factors associated with immediate breast reconstruction (IBR) using a large population-based registry. We hypothesized that rates of IBR have increased since passage of the Women’s Health and Cancer Rights Act of 1998.

Methods—The SEER (Surveillance, Epidemiology and End Results) database was used to evaluate Stage I–III breast cancer (BC) patients who underwent total mastectomy from 1998–2008. Univariate and multivariate analyses were performed to study predictors of IBR.

Results—Of 112,348 patients with BC treated by mastectomy, 18,001 (16%) had IBR. Rates of IBR increased significantly from 1998–2008 ($p < 0.0001$). Use of IBR significantly decreased as patient age increased ($p < 0.0001$), as stage increased ($p < 0.0001$), and as the number of positive lymph nodes increased ($p < 0.0001$). Estrogen receptor +/progesterone receptor + (ER+/PR+) patients had significantly higher IBR rates than ER–/PR– patients ($p < 0.0001$). IBR was used in 3615 of 25,823 (14.0%) of patients having post-mastectomy radiation (XRT) and in 14,188 of 86,513 (16.4%) of those not having XRT ($p < 0.0001$).

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Conclusions—The utilization of IBR has increased significantly over the last decade. IBR was found to be significantly associated with age, race, geographical region, stage, ER, grade, LN status, and XRT ($p < 0.0001$).

Keywords

SEER; breast cancer; mastectomy; immediate breast reconstruction

INTRODUCTION

Approximately 230,500 women were diagnosed with invasive breast cancer during 2011 in the United States[1]. Historically, approximately one-third of breast cancer patients have been treated with mastectomy and the remaining two-thirds had breast-conserving surgery, [2,3] resulting in a possible 76,833 potential candidates for reconstruction in 2011. About 17% of women undergoing mastectomy from 1998 to 2002 had either immediate or delayed breast reconstruction[4]. Immediate breast reconstruction (IBR) has increasingly gained clinical acceptance as an integral component of multidisciplinary care, and is generally considered a standard of care approach for appropriately selected mastectomy patients. IBR has the advantage of retaining the skin envelope, which results in improved aesthetic outcomes, fewer operations to achieve the reconstructive goals, and potential psychological benefits to the patient[5]. The risk of masking recurrence with breast reconstruction is minimal[6–9].

However, IBR has been shown to have higher complication rates, approaching 40% compared to 17% for delayed breast reconstruction[10,11]. Our institution has previously reported that immediate breast reconstruction is associated with a statistically significant increased risk of surgical site infection in patients undergoing mastectomy (3.5% vs. 2.5%) [12]. Complications may increase the time interval required for wound healing and possibly delay the delivery of adjuvant chemotherapy or radiotherapy (XRT)[13]. Although Alderman *et al.* demonstrated that IBR was associated with a modest but statistically significant delay in initiating chemotherapy, Rey *et al.* and Peled *et al.* reported that IBR was not associated with increased complications and did not cause a delay in chemotherapy[14,15]. A primary factor involved with the decision to utilize IBR is post-mastectomy radiation, which may compromise the results of both autologous and implant-based reconstructions and limit use of IBR in patients for whom post-mastectomy radiation is anticipated[16–18]. Furthermore, Alderman *et al.* found that only one-third of breast cancer patients reported that a general surgeon discussed the option of breast reconstruction with them at the time of surgical decision-making, suggesting that selection bias may be an important barrier to IBR[19]. The rates of post-mastectomy IBR are also affected by other variables, such as patient comorbidities, obesity, smoking, and personal preferences[20,21].

The Surveillance, Epidemiology and End Results (SEER) database of the National Cancer Institute contains data from about 28% of the breast cancer patients diagnosed annually in the United States, and it has previously been used to study trends in breast reconstruction[20,22,23],[24]. Previous evaluations of the SEER database from 1998 to 2002, did not demonstrate increased rates of breast reconstruction following passage of the

Women's Health and Cancer Rights Act of 1998[24,25]. These studies did, however, detect differences in rates of IBR associated with age, race, geographical location, and XRT. The purpose of this study was to examine trends in rates of IBR using this more contemporary SEER cohort, from 1998 to 2008[24]. It should be noted that, although the SEER 13 database did not report receipt of chemotherapy, endocrine therapy, or trastuzumab, prior analyses have demonstrated that ER status did correlate with the probability of using adjuvant systemic therapy²⁶⁻²⁸.

We hypothesized that rates of IBR have increased since passage of the Women's Health and Cancer Rights Act of 1998. A secondary aim of our study was to identify patient, tumor, treatment and geographical factors correlated with use of IBR in this large population-based study of patients treated by mastectomy for newly diagnosed Stage I-III breast cancer.

PATIENTS AND METHODS

De-identified patient information for the years 1998-2008 was collected from the prospectively maintained SEER registry and included in our study. The SEER 17 registry was used for our analysis and this includes data from the SEER 13 registry (Atlanta, Connecticut, Detroit, Hawaii, Iowa, New Mexico, San Francisco-Oakland, Seattle-Puget Sound, Utah, Los Angeles, San Jose-Monterey, Rural Georgia and the Alaska Native Tumor Registry), plus Greater California, Kentucky, Louisiana and New Jersey. The patients in the Alaska Native Tumor Registry were excluded since a significant proportion of their patients receive IBR out of state, if needed. Patients were classified according to five racial groups: White, Black, American Indian/Alaska Native, Asian/Pacific Islander, and Hispanic origin.

Three types of variables were included in the analysis: 1) patient demographics- age, race, and geographical region; 2) tumor characteristics-ER/PR status, axillary lymph node status, histologic type, tumor grade, and tumor stage; and 3) treatment variables-use of XRT and IBR. Reconstruction within the first 4 months after mastectomy was defined as IBR, according to the SEER database field code definitions. Data regarding the distinction between immediate and early-delayed reconstruction were not available in the SEER database, nor were there data on reconstruction delayed more than 4 months post-mastectomy. Reconstructive procedures exclusively associated with the contralateral breast were excluded from our study.

Inclusion and exclusion criteria

Female patients with a new diagnosis of breast cancer who underwent mastectomy for Stage I-III breast cancer between the years 1998-2008 were included in the study. Patients who had subcutaneous mastectomy (code 30), simple mastectomy (40-49, 75), modified radical mastectomy (50-59, 63), radical mastectomy (60-62, 64-69, 73-74) and mastectomy (80) were included in the study. Patients who had partial mastectomy or extended radical mastectomy were excluded from the study. Patients who had any prior history of any type of cancer were also excluded (n=26,511). Patients with invasive ductal, lobular, or combined ductal and lobular carcinoma were included, but those with purely in-situ ductal or lobular carcinoma were excluded. Those with Stage IV breast cancer or a diagnosis of inflammatory

breast cancer were excluded. Patients who had no data regarding ER/PR status or XRT were excluded. Follow up data through 2010 was available for analysis.

Statistical Analysis

The Chi-squared test was used to examine the association between reconstruction rate and patient/tumor characteristics. The relative risk was estimated for each variable. The Cochran-Armitage trend test was performed to investigate the underlying trend for reconstruction rate. For the multivariate analysis, the logistic regression model was employed to assess predictive factors for breast reconstruction. For each variable, adjusted relative risk (RR) with 95% confidence intervals (CIs) were computed. All statistical analyses were performed with SAS 9.2 (SAS Institute Inc., Cary, NC). Tests were deemed to be significant at a p-value of 0.05.

RESULTS

Patient and Disease Characteristics

From January 1, 1998–December 31, 2008, there were 371,309 patients diagnosed with breast cancer who had data recorded in SEER 13. Of these, 112,348 patients (30.2%) had mastectomy and met all inclusion/exclusion criteria. There were 18,001 (16.0%) patients who had IBR after mastectomy. Table I summarizes the patient demographics and tumor characteristics of the study population.

Annual IBR Rates

As demonstrated in Figure 1, IBR rates steadily increased over time, from 712 (11.7%) in 1998 to 2774 (21.7%) in 2008, a near doubling in rates during this timeframe ($p < 0.0001$). A modest 2.1% increase in IBR rates was found from 1998 to 2002, with rates increasing from 11.7% to 13.8%. However, from 2002 to 2008 the rate increase was noted to be 7.9%, nearly 4 times the increase noted from 1998 to 2002, indicating that most of the increase in IBR rate was associated with the latter portion of the study.

Patient Variables

Univariate (Table II) and multivariate (Table III) analyses were performed correlating patient, tumor, and treatment variables with likelihood of IBR. IBR rates significantly decreased as patient age increased. Patients on the Pacific Coast and in the Southwest were significantly less likely to have IBR than those in the East. Non-white patients were significantly less likely to have IBR than White patients.

Tumor and Treatment Variables

Univariate (Table II) and multivariate (Table III) analyses were performed correlating tumor and treatment variables with likelihood of IBR. IBR rates significantly decreased as tumor size increased, grade increased, the number of positive nodes increased, and stage increased. While there was not a significant difference found in rates of IBR for patients with negative versus 1–4 positive nodes, the likelihood of IBR was decreased in patients with more positive nodes (5–10 positive nodes (RR-0.82, $p < 0.0001$, (0.77–0.88)) and >10 positive

nodes (RR-0.79, $p<0.0001$, (0.73–0.85))). Patients who were both ER+ and PR+ had a significantly higher rate of IBR (16.2%) when compared with patients who were ER– and PR– (14.5%) and with patients who were either ER+ or PR+ (13.9%) ($p<0.0001$ and $p<0.0001$, respectively). Patients with Stage I ER+/PR+ cancers were 1.9 times more likely to have IBR than those with Stage III ER–/PR– cancers ($p<0.0001$). Patients with Stage III ER+/PR+ cancers were 1.3 times more likely to have IBR than patients with Stage III ER–/PR– tumors ($p<0.0001$).

IBR and XRT

In this study population, IBR was performed in 3615 of 25,823 (14.0%) patients treated with post-mastectomy XRT and in 14,188 of 86,513 (16.4%) of those not having XRT ($p<0.0001$). Although the absolute difference in the rates of IBR was relatively small, a statistically significant difference was found in rates of IBR between the radiated and non-radiated mastectomy patients.

DISCUSSION

The passage of the Women's Health and Cancer Rights Act of 1998 laid the groundwork for increasing utilization of IBR in the United States, as this Federal legislation mandated that insurance companies offering mastectomy must also provide coverage for all stages of reconstruction²⁹. The effects of this legislation was evaluated in the past by Alderman *et al.*, who reported there was no significant increase in the annual rates of IBR between 1998–2002 based on the SEER registry[25]. In contrast, the current study has demonstrated an increase in immediate reconstruction rates from 1998 to 2008. The majority of the increase in this rate seems to have occurred after 2002, explaining why the earlier SEER analyses failed to note a difference in IBR rates. To our knowledge, this is the first SEER-based study to document this observation.

This nationwide trend has been apparent in other large population-based studies, including analysis of the Nationwide Inpatient Sample (37.8% IBR) by Albornoz *et al.*[26] as well as non-population based databases, such as the National Comprehensive Cancer Center Network consortium (42% IBR) by Christian *et al.*[27] However, the study by Albornoz *et al.*, while capturing a large cross section of mastectomy treated patients, was heterogeneous in that it included patients who had prophylactic mastectomy without cancer diagnosis as well as patients with ductal carcinoma in situ (DCIS). Similarly, the study by Christian *et al.* included DCIS patients; as nearly all DCIS patients treated by mastectomy, in the absence of co-morbidities, could be offered immediate breast reconstruction without concern for the need for adjuvant radiotherapy, we purposely excluded this diagnosis for our analysis. The objective of the present study was to determine rates of IBR in an updated SEER cohort restricted to patients with newly diagnosed Stage I–III breast cancer, taking into consideration the effect of available relevant patient, tumor and treatment variables captured by the National Cancer Institute's SEER registry. The study by Christian *et al.* reflects IBR rates at a subset of comprehensive cancer centers and thus the impressive rate of IBR reported may not reflect national practice patterns for rates of IBR in community-based practice.

The increased rates of IBR may provide insight into changing nationwide trends in multidisciplinary oncological care from 1998–2008, such as increasing use of neoadjuvant treatment, skin-sparing mastectomy, and multidisciplinary decision-making prior to therapy (tumor boards). The advent of skin-sparing mastectomy paved the way to the development of multiple options for autologous and implant-based IBR. Skin-sparing mastectomy has been demonstrated in single institution studies to be associated with equivalent local, regional, and systemic recurrence rates as total mastectomy without reconstruction^{30–32}. In the current study, race/ethnicity and geographic region had a particularly strong impact on rates of IBR, suggesting that there are still barriers to access for post-mastectomy breast reconstruction. The evaluation of the SEER database performed by Agarwal *et al.* demonstrated a similar trend correlating IBR with demographics in 2002. However, it could also be explained by the higher likelihood of diagnosis at more advanced stage disease. Unlike Agarwal *et al.*'s paper, which focused on all stages of breast cancer and emphasized analyses of income and demographic variables, our study sought to look at the trends in IBR for patients with newly diagnosed Stage I-III breast cancer, in the context of relevant covariates.

During much of the time period of this study, post-mastectomy XRT was used in patients with 4 positive lymph nodes or cancers >5 cm. This treatment pattern probably accounted for the observed similar rates of IBR in node-negative patients and those with 1–4 positive lymph nodes, and for the higher rates in node-negative patients than in those with 5 positive nodes. It most likely also accounted for the observed decreasing use of IBR as tumor size increased. The current study also revealed an increased use of IBR for Stage III patients when compared to previous SEER-based studies²⁴. This trend was probably influenced by published reports, such as one in which XRT did not increase complication rates with IBR or one in which the indications for IBR were expanded to include patients with locally advanced disease who had good responses to neoadjuvant chemotherapy^{33,34}. The relatively small but statistically significant difference in IBR rates for ER+/PR+ (16.2%) versus ER-/PR- (14.5%) patients may reflect clinical factors not collected in the SEER database, such as the increased utilization of systemic chemotherapy in ER- patients.

Differences in rates of IBR for patients having (14%) versus not having (16.4%) post-mastectomy XRT, although statistically significant, were of a smaller magnitude than would be expected^{4,21,25}. A survey conducted by the American Society of Plastic Surgeons in 2010 revealed that 81% of surgeons did not perform IBR in patients requiring post-mastectomy XRT¹⁹. However, trends in IBR reflect increased use of these techniques despite the receipt of adjuvant radiation. This increase in IBR has been speculated to occur for a number of reasons. Improvements in delivery mechanisms for radiation in the presence of both implant and autologous IBR coupled with patient demand for IBR, have allowed surgeons and radiation oncologists to create innovative mechanisms of offering the benefits of IBR to a wider patient population than previously reflected in the literature. These types of innovations could have also accounted for the small but statistically significant 2.4% difference in IBR rates in patients who did versus did not receive post-mastectomy XRT. It should be noted that patients who had a prior history of any cancer were left out of this

analysis, thus excluding those who had been previously treated with breast conservation surgery and radiation, as well as those who had any previous cancer-directed treatment.

Our study was limited by the fact that the SEER database did not include information regarding delayed reconstruction, chemotherapy, endocrine therapy, trastuzumab, or other factors that may have influenced the surgical decision-making process including comorbidities, smoking, obesity, previous abdominal operations, or patient preferences. Nonetheless, our study provided updated information regarding trends in the use of IBR in the United States using a large, prospective, contemporary database that represents a cross section of current breast cancer treatment in the United States. Furthermore, while our study demonstrated increased rates of IBR since 1998, it is unlikely that the Women's Health and Cancer Rights Act of 1998 was the sole cause of this change in practice. For example, our study does not control for the variety of payers or other socioeconomic variables that may have confounded access to IBR, nor does our study control for the effect of patient comorbidities on decision making for IBR. In addition, while our study may have suggested regional differences in rates of IBR, we were unable to determine whether these differences reflected variability in access to reconstructive surgeons versus differing viewpoints on appropriate indications for immediate post-mastectomy reconstruction.

CONCLUSIONS

The utilization of IBR for newly diagnosed breast cancer patients has increased significantly over the last decade. Using multivariate analysis, IBR was found to be significantly associated with age, race, geographical region, stage, ER, grade, LN status, and XRT ($p < 0.0001$). Differences in rates of IBR for patients having versus not having post-mastectomy XRT were of a smaller magnitude than would be expected but were statistically significantly different. Several potentially confounding treatment variables, such as use of adjuvant or neoadjuvant chemotherapy, patient preferences, type of insurance and availability of reconstructive surgeons in the regions studied cannot be quantified using the SEER database. Nonetheless, this study is the first SEER analysis to document that rates of IBR have increased since passage of the Women's Health and Cancer Rights Act of 1998. However, less than one in four mastectomy patients in this SEER study cohort received immediate breast reconstruction. Given advances in reconstructive techniques and acceptance of incorporating IBR into the multidisciplinary care of breast cancer patients, further increases in rates of immediate breast reconstruction are likely to be noted going forward as indications for IBR appear to be evolving.

Acknowledgments

The authors take full responsibility for the content of the paper but thank Mary Knatterud, Ph.D. (supported by the Department of Surgery of the University of Arizona), for her copyediting.

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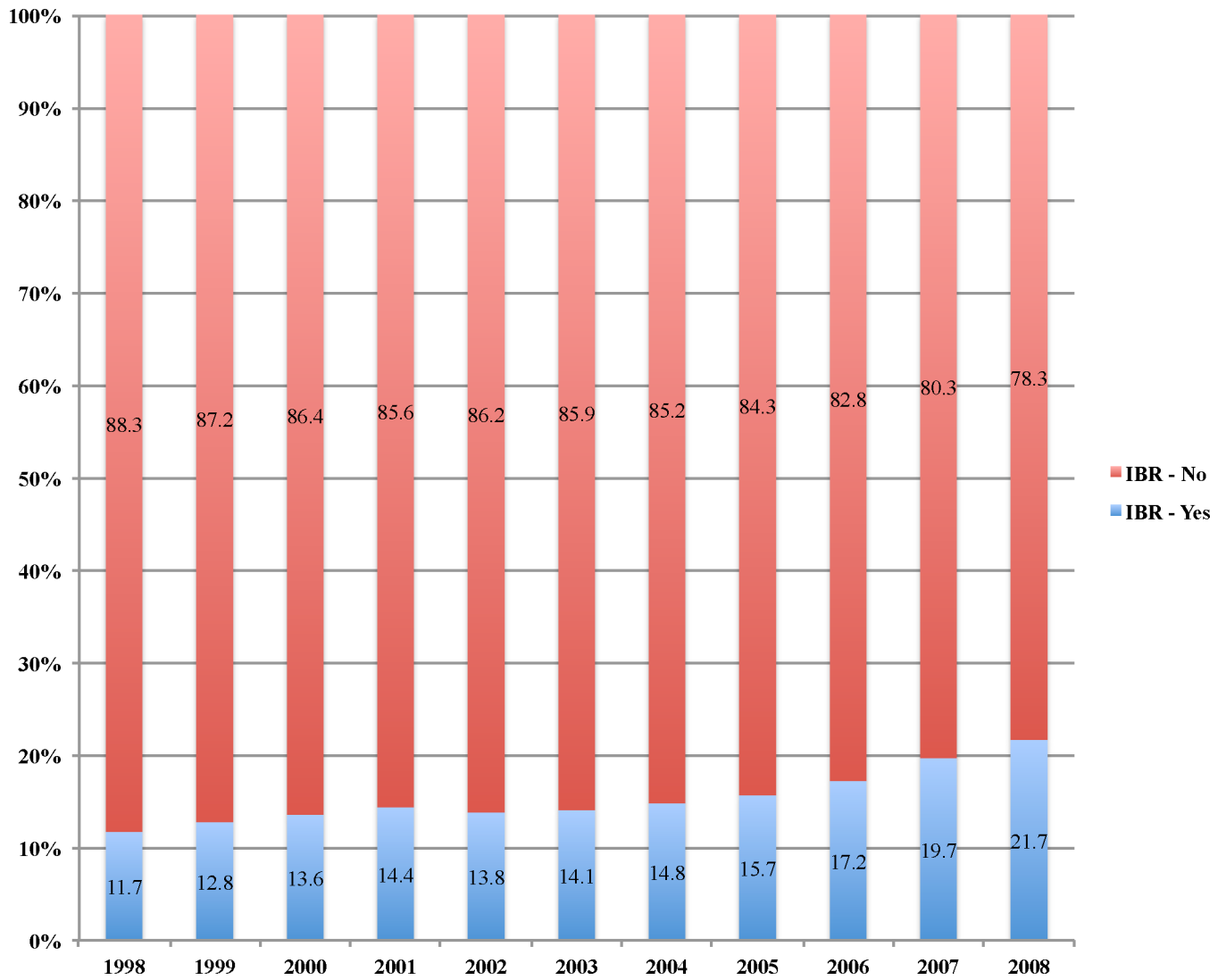


Figure 1.
IBR rates increased from 1998–2008. A near doubling of rates of IBR occurred when comparing rates in 1998 to 2008.

Table I

Patient demographics and tumor characteristics

Characteristics	Number	%
Age		
20–29 years	797	0.7
30–39 years	8092	7.2
40–49 years	24,105	21.5
50–59 years	26,842	23.9
60–69 years	22,294	19.8
70–79 years	19,038	17.0
80+ years	11,180	10.0
Race/ethnicity		
White	80,325	71.8
Black	10,120	9.1
American Indian / Alaska Native	401	0.4
Asian or Pacific Islander	9981	8.9
Hispanic		
Geographic Region		
East	34,411	30.6
Northern Plains	14,539	12.9
Pacific Coast	57,626	51.3
Southwest	5772	5.1
Regional lymph nodes # positive		
0	57,483	51.2
1–4	34,585	30.8
5–10	10,790	9.6
>10	9490	8.4
Grade		
1	16,082	15.3
2	42,738	40.5
3	44,656	42.4
4	1943	1.8
Stage		
I	37,796	34.8
II	54,140	49.9
III	16,643	15.3
ER		
Positive	84,008	74.8
Negative	28,340	25.2

Characteristics	Number	%
PR		
Positive	69,251	63.1
Negative	40,557	36.9
Radiation		
Yes	25,823	23.0
No	86,513	77.0

Table II

Association of patient demographics and tumor characteristics with IBR (Univariate Analysis).

Characteristics	Reconstruction Rate (%)	P-value for the difference	P-value for the trend
Age			
20–29yrs	32.6		
30–39yrs	30.5		
40–49yrs	27.6		
50–59yrs	20.1	<0.0001	<0.0001
60–69yrs	10.1		
70–79yrs	3.3		
>80yrs	0.8		
Geographical Region			
East	20.3		
Northern Plains	18.7		
Pacific Coast	12.4	<0.0001	NA
Southwest	16.0		
Race/Ethnicity			
White	17.5		
Black	13.4		
American Indian/Alaska Native	10.0		
Asian or Pacific Islander	9.5	<0.0001	NA
Hispanic	11.8		
Stage			
I	19.0		
II	15.3	<0.0001	<0.0001
III	11.4		
Grade			
1	16.8		
2	16.2		
3	15.4	<0.0001	<0.0001
4	15.0		
Radiation			
No	16.4		
Yes	14.0	<0.0001	NA
Number of positive nodes			
0	17.3		
1–4	16.2	<0.0001	<0.0001
5–10	11.8		
>10	10.1		

Characteristics	Reconstruction Rate (%)	P-value for the difference	P-value for the trend
ER			
Positive	16.2		NA
Negative	14.9	<0.0001	
PR			
Positive	16.8		
Negative	14.5	<0.0001	NA
Tumor size			
<2cm	19.4		
2–5cm	13.9	<0.0001	<0.0001
>5cm	11.8		

Table III

Association of patient demographics and tumor characteristics with IBR (Multivariate Analysis).

Characteristics	Adjusted RR	95% CI	p-value
Age			
20–29 years	1.00	-	-
30–39 years	0.88	(0.78, 0.98)	0.02
40–49 years	0.75	(0.68, 0.83)	<0.0001
50–59 years	0.53	(0.48, 0.58)	<0.0001
60–69 years	0.25	(0.23, 0.28)	<0.0001
70–79 years	0.08	(0.07, 0.09)	<0.0001
80+ years	0.02	(0.01, 0.02)	<0.0001
Race/ethnicity			
White	1.00	-	-
Black	0.65	(0.61, 0.69)	<0.0001
American Indian	0.52	(0.38, 0.70)	<0.0001
Asian or Pacific Islander	0.54	(0.50, 0.58)	<0.0001
Hispanic	0.66	(0.63, 0.69)	<0.0001
Geographic Region			
East	1.00	-	-
Northern Plains	0.97	(0.93, 1.003)	0.07
Pacific Coast	0.67	(0.65, 0.69)	<0.0001
Southwest	0.78	(0.74, 0.84)	<0.0001
Number of positive nodes			
0	1.00	-	-
1–4	0.96	(0.92, 1.009)	0.11
5–10	0.82	(0.77, 0.88)	<0.0001
>10	0.79	(0.73, 0.85)	<0.0001
Grade			
1	1.00	-	-
2	0.96	(0.93, 1.009)	0.06
3	0.90	(0.87, 0.94)	0.03
4	0.88	(0.79, 0.98)	<0.0001
Stage			
I	1.00	-	-
II	0.93	(0.88, 0.98)	<0.0001
III	0.84	(0.77, 0.91)	<0.0001
Tumor size			
<2cm	1.00	-	-
2–5cm	0.82	(0.79, 0.85)	<0.0001

Characteristics	Adjusted RR	95% CI	p-value
>5cm	0.75	(0.71, 0.80)	<0.0001
ER			
Positive	1.00	-	
Negative	0.89	(0.86, 0.94)	<0.0001
PR			
Positive	1.00	-	-
Negative	0.98	(0.94, 1.02)	0.33
Radiation			
No	1.00	-	-
Yes	0.82	(0.79, 0.85)	<0.0001

RR=relative risk