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Breast-Conservation Therapy after Neoadjuvant Chemotherapy Does Not Compromise 10-year Breast Cancer Specific Mortality

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Abstract

Objectives: Neoadjuvant chemotherapy can increase the rate of breast-conserving surgery by downstaging disease in patients with breast cancer. The aim of this study was to determine whether patients who received neoadjuvant chemotherapy have equal survival after breast-conservation therapy compared to mastectomy.

Methods: Using the New Jersey State Cancer Registry (NJSCR) patients with a primary breast cancer diagnosed between1998–2003 who underwent neoadjuvant chemotherapy were selected

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(n=1,468). Of those, only patients who received lumpectomy plus radiation (n=276) or mastectomy without radiation (n=442) were included in the analysis. The main outcome measured included 10-year breast cancer specific mortality, with ninety percent of patients with known vital status through the end of 2011.

Results: Baseline characteristics did not differ significantly between the breast-conservation and mastectomy without radiation groups except with respect to summary stage and lymph node involvement. After propensity score matching these differences were no longer statistically significant; however, both estrogen and progesterone status achieved statistical significance. The Kaplan-Meier survival curve showed that the breast-conservation group had significantly higher breast cancer specific survival than the mastectomy group (p=0.0046). After adjusting for the propensity score in the regression model, the breast-conservation group continued to show significantly better survival than the mastectomy group (HR=0.46 95% CI 0.27–0.78).

Conclusions: This study is consistent with previous research showing that breast-conserving surgery after neoadjuvant chemotherapy does not reduce breast cancer-specific survival. In fact, patients undergoing breast-conservation after neoadjuvant therapy appeared to have better survival than patients undergoing mastectomy without radiation.

Keywords

Breast cancer; breast conservation therapy; downstage; neoadjuvant chemotherapy

Introduction

Neoadjuvant chemotherapy may increase the use of breast-conservation surgery among patients with limited breast cancer[1, 2]. Breast-conservation can result in improved body image, cosmesis, and sexual function compared to those undergoing mastectomy[3–5]. The National Surgical Adjuvant Breast and Bowel Project (NSABP) B18 trial was the seminal trial examining the sequencing of cytotoxic chemotherapy with respect to local therapy of breast cancer[1, 2, 6]. This trial demonstrated that 1) neoadjuvant chemotherapy produced disease-free and overall survival similar to those with adjuvant, postoperative chemotherapy; 2) response to induction chemotherapy correlated significantly with survival; and, 3) neoadjuvant chemotherapy could increase breast-conservation in woman initially scored as being appropriate for mastectomy[1].

With respect to the ipsilateral breast tumor recurrence (IBTR) rates, several important lessons were evident from the NSABP B18 trial. IBTR rates were similar in the preoperative and postoperative chemotherapy arms (7.9% vs 5.8%)[7]. Of women who were initially scored as appropriate for mastectomy (n=256), 27% became eligible for breast-conserving therapy (BCT)--their IBTR rate was 14.3%. Women who were scored as candidates for BCT at the outset had an IBTR rate of 6.9%. No differences were described between these two groups of women with respect to overall survival (OS), disease free survival (DFS) or breast cancer specific mortality (BCSM). Chen and colleagues further described outcomes in women undergoing BCT after neoadjuvant chemotherapy in a cohort of 340 women treated at the MD Anderson Cancer Center (MDACC)[8]. They reported 5-year actuarial IBTR and locoregional recurrence (LRR) rates of 5% and 9%, respectively. They did not report on

survival endpoints[8]. Rastogi et al recently updated results of the B18 trial pooled with results from B27, affirming the benefit of neoadjuvant chemotherapy in premenopausal women and the added value of pre-operative taxanes in improving response rates[6]. Specifically, the NSABP B27 trial revealed that adding docetaxel to preoperative doxorubicin and cyclophosphamide (AC) significantly improved disease free survival among those who had a clinical partial response to AC[9].

Still, the specific question of whether downstaged breast-conservation patients have equal survival to similar patients who undergo a mastectomy after preoperative chemotherapy has not been tested in additional cohorts. This issue may be particularly relevant for women who have initially “large” (T3 or perhaps even T2 > 3cm) tumors. These are the women who are most likely to receive neoadjuvant chemotherapy in current practice. The aim of this study was to determine whether patients with breast cancer who undergo breast-conservation therapy after induction chemotherapy have similar breast cancer-specific survival rates compared to New Jersey residents who were diagnosed with breast cancer and underwent mastectomy. We used population-based statewide surveillance data, including first course treatment and survival, from the New Jersey State Cancer Registry (NJSCR).

Material and Methods

Incident cases of breast cancer were obtained from the New Jersey State Cancer Registry (NJSCR), which is a statewide population-based cancer incidence registry that has served New Jersey’s diverse population of approximately 8.8 million people since 1979. The NJSCR is a member of the National Cancer Institute’s Surveillance, Epidemiology and End Results (SEER) Program and the Centers for Disease Control and Prevention’s National Program of Cancer Registries (NPCR) with the highest quality incidence and survival data. New Jersey regulations require the reporting of all newly diagnosed cancer cases to NJSCR within six months of diagnosis. Data for each patient includes demographic and clinical information on each cancer diagnosis (such as the anatomic site, histological type, summary stage, and first course of treatment). SEER uses all information obtained through completion of the first course of surgery or within 4 months, whichever is longer, to assign a summary stage of in situ, localized, regional, distant or unknown. This is based on a combination of clinical and pathological stage, typically whichever is higher. Vital status information is updated annually through linkages with state and national data sources, and for deceased patients the underlying cause of death is included. The primary site, behavior, grade, and histology of each cancer are coded according to the International Classification of Disease for Oncology (ICD-O), 3rd edition[10].

A data set was created using the NJSCR February 2014 data file, which included all female breast cancer patients diagnosed in 1998–2003. Follow-up information is included through December 31, 2011. The cases selected for analysis included patients with a primary breast cancer who underwent neoadjuvant chemotherapy (n=1,468). Of those, only patients who received lumpectomy plus radiation (n=276) or mastectomy without radiation (n=442) were included in the analysis. We excluded patients who had lumpectomy without radiation, as this would be considered a significant departure from standard practice. We also excluded patients who had mastectomy plus post-mastectomy radiation therapy (PMRT), as we

expected these patients to have additional high-risk features (i.e., the usual indications for PMRT), and that this would confound our comparison.

The lumpectomy group included patients who had breast-conserving surgery for removal of the gross primary tumor and some of the breast tissue; while mastectomy patients had subcutaneous mastectomy, total mastectomy or radical mastectomy. The demographic factors included age, race (white, black, other races), the census tract poverty level (percent of population below poverty threshold), and health insurance at diagnosis (private, Medicare and other insurance, uninsured and Medicaid, and unknown). Summary stage, lymph node involvement, and estrogen and progesterone receptor status were used as prognostic factors.

Breast cancer specific survival was calculated in months from the date of diagnosis to the date of death, or date of last known alive, or December 31, 2011 (the study cut-off date). The missing components for date of diagnosis and date of last contact were assigned using an algorithm developed by the National Cancer Institute's (NCI) SEER Program[11], which sets a missing date component to the midpoint of the possible values.

The general associations of surgery types and demographic and prognostic factors were tested using Chi-square. To minimize the bias caused by the differences in summary stage, lymph node involvement, and estrogen and progesterone receptor status in the two surgery groups, a propensity score matching method was used to select samples from the original cohort[12]. The baseline variables used in the logistic regression model to calculate the probability scores for each surgery group included age, summary stage, lymph node involvement, and estrogen and progesterone receptor status. Two equal samples were selected by matching the probability scores with a radius of 0.2.

The Kaplan-Meier survival rates were estimated and hazard ratios (HR) calculated using Cox regression method using the samples from the matched pairs. The propensity scores were adjusted as a continuous variable in the regression model. Finally, to compare risk strata, survival curves were calculated for the breast-conservation therapy and mastectomy groups based on the presence or absence of nodal involvement. Statistical Analysis System (SAS) 9.4 was used for all analyses. Institutional review board approval for this study was granted by the Rutgers Robert Wood Johnson Medical School IRB.

Results

Of the 1,468 cases of newly diagnosed breast cancer from 1998–2003 in NJSCR who received neoadjuvant chemotherapy followed by surgical intervention, 276 had breast-conserving therapy (BCT, lumpectomy plus radiation) and 442 had mastectomy without radiation. The remaining cases were excluded because they received lumpectomy without radiation (n=117, many of these were presumably errors in reporting since the standard of care is for all patients who undergo lumpectomy to also receive radiation) or mastectomy with radiation (n=197, these patients likely had poor prognostic indicators qualifying them for post-mastectomy radiation). Baseline characteristics for the two groups are reported in Table 1. On average, patients in the BCS group had an earlier summary stage and less lymph node involvement than the mastectomy group, and this did achieve statistical significance.

Age at diagnosis, race, residence area poverty level, health insurance and estrogen and progesterone receptor status did not differ significantly between the two groups (Table 1). After adjusting, the median follow-up time was 110.5 months for the BCS group and 106.0 months for mastectomy patients.

The samples for propensity score matching included 220 patients in each group. The differences between groups including summary stage at diagnosis and lymph node involvement were no longer statistically significant after propensity adjustment, however both estrogen and progesterone receptor status did gain statistical significance (Table 2). The Kaplan-Meier survival curve showed that the BCT patients had higher breast cancer specific survival rates than the mastectomy group, and this reached statistical significance (Figure 1, p=0.0046). The survival range was 17 months to 118 months for the BCS group and 7 to 116 months for women who received mastectomy only. Even after adjusting for the propensity score in the regression model, the BCT group continued to have better survival than the mastectomy group (HR=0.46 95% CI 0.27–0.78). Although not statistically significant (Figure 2, p=0.70), survival curves that were grouped according to both treatment type and nodal status showed that, even when the analysis was restricted to patients without lymph node involvement, BCT patients had improved survival compared to mastectomy alone. Similarly, among patients who were lymph node positive, there was a survival advantage for BCT compared to those who underwent mastectomy without radiation, although not statistically significant (Figure 2, p=0.10).

Discussion

In this analysis we examined 10-year breast cancer specific mortality as a function of choice of BCS after neoadjuvant chemotherapy. We hypothesized that breast-conserving therapy after induction chemotherapy would not compromise long-term cure of breast cancer. Our findings are consistent with those reported by the NSABP trialists and by Chen et al, demonstrating that breast-conservation after neoadjuvant chemotherapy can be a safe alternative to more invasive surgery.

Potential sources of bias may exist in this non-randomized comparison. For example, some patients in the mastectomy group may have required a larger operation because they had less tumor shrinkage after chemotherapy. Although we attempted to reduce this bias by using propensity score matching, it is certainly possible that the mastectomy group had a poorer prognosis at the outset. In addition, not all patients who underwent lumpectomy were necessarily “downstaged” (some may have been suitable for lumpectomy to begin with and therefore had a more favorable prognosis at the outset). Furthermore, this was a retrospective study with data drawn from NJSCR, a population based registry that covers 8.8 million people. As such, there are obvious limitations with the consistency of data entry. Another limitation for this study is the lack of some important clinical factors such as tumor size and missing radiation and chemotherapy data due to the incompleteness of the information in the database. As a result of these limitations, one must recognize that the suggestion that radiation may reduce systemic relapse has not been adequately studied, and therefore should not influence clinical decision making.

Our analysis also demonstrated an unexpected finding. We found that patients undergoing breast-conserving therapy appeared to have improved breast cancer specific survival compared to mastectomy. Patients who had post-mastectomy radiation therapy had significantly worse 10-year outcome in our initial analysis and were ultimately excluded from this study. We attributed their poor outcomes to the higher risk profile that was likely associated with these patients (i.e., features associated with stage IIIB-C disease). In contrast, we felt that women undergoing breast-conservation (lumpectomy plus radiation) and those undergoing mastectomy without radiation were likely to have comparable risk profiles. In a propensity-matched comparison of these two groups, we found significantly *improved* 10-year breast cancer survival with breast conservation, and this did achieve statistical significance. An obvious explanation for this finding is the potential for hidden biases, despite the propensity matching. An alternative but plausible explanation for this finding is that the addition of regional nodal radiotherapy is driving this observed improvement. Similar findings have been reported by others.

AbdulKarim et al reported results on a retrospective cohort of triple-negative breast cancer patients (n=768) and compared outcomes stratified by type of local-regional therapy[13]. Patients who received BCT had better local-regional control and better survival than patients who received modified radical mastectomy (MRM) on univariate analysis. On multivariate analysis, initial BCT continued to predict improved LRR but not OS. This improvement in 5-year local-regional control with breast-conservation was also observed in patients with T1-T2N0 disease. Local treatment strategy remained a predictor of LRR on multivariate analysis in this group. Similarly, Whelan and colleagues have reported results from the MA.20 trial[14]. In this trial, 1832 high-risk node-negative (10%) or node-positive patients were randomly assigned to whole breast radiation alone or included regional draining lymph nodes after breast-conserving surgery. With a median follow-up of 9.5 years, the addition of regional nodal radiation therapy (RT) improved 5-year local-regional control, distant-metastasis free survival (86.3% vs 82.4%, p=0.03), and disease-free survival (82.0% vs. 77.0%; p=0.01). The European Organization for Research and Treatment of Cancer (EORTC) 22922–10925 trial also randomized patients to additional irradiation of the internal mammary and supraclavicular nodes versus not and, with a median follow-up of 11 years, demonstrated statistically significant improvements in survival[15]. A recent meta-analysis by Budach *et al.* showed that combined results of the National Cancer Institute of Canada (NCIC) Clinical Trials Group (CTG) MA.20 and EORTC 22922–10925 trials revealed a statistically significant improvement in overall survival (HR=0.85 95% CI 0.75 – 0.96)[16]. Our results, taken together with these data, appear to lend hort to the idea that regional lymphatic radiation can lead to breast cancer cure. We attempted to further explore this difference among node-positive and node-negative patients, and although similar differences existed in both, this did not achieve statistical significance.

The inclusion of regional nodes is not known in this study cohort. However, even when radiotherapy is directed to the breast only, the lower axilla frequently receives therapeutic doses of radiation incidentally. In any case, radiotherapy is often a more radical and comprehensive treatment than modified radical mastectomy alone, especially when the internal mammary and supraclavicular nodes are purposefully treated. Although our findings

should not guide clinical treatment, our study calls for further exploration of the comparative effectiveness of these treatments in other population-based datasets.

In summary, this study showed improved breast cancer specific survival in patients who underwent lumpectomy plus radiation compared to mastectomy alone. While a greater percentage of patients undergoing mastectomy did have positive lymph nodes this was controlled for by both propensity score analysis and survival curves based on nodal status within the groups. Although these results did not reach statistical significance when nodal status was controlled for, certain trends still exist that merit further investigation. Furthermore, these findings corroborate earlier studies that breast-conservation therapy following preoperative chemotherapy does not lead to poorer outcomes.

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Test of Equality over Strata			
Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	8.0371	1	0.0046
Wilcoxon	7.9025	1	0.0049
-2Log(LR)	8.0760	1	0.0045

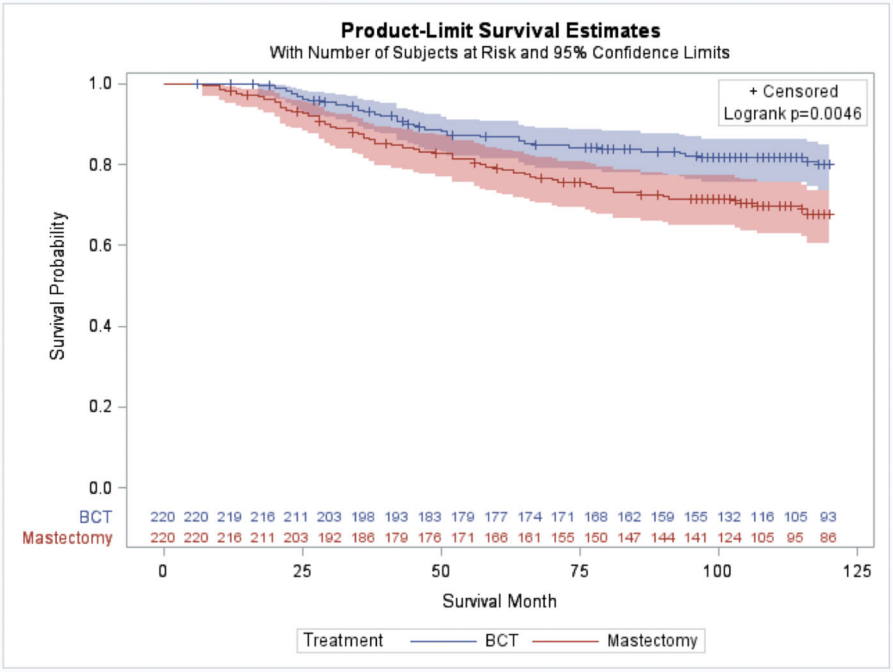

Figure 1.

Breast cancer specific survival rate for breast cancers treated with chemotherapy followed by breast-conserving therapy (lumpectomy plus radiation) or mastectomy without radiation -- Matched Pair Samples (n=220 for each group)

Adjustment for Multiple Comparisons for the Logrank test	
	p-value
BCT/Lymph- vs Mastectomy/Lymph-	0.70
BCT/Lymph- vs BCT/Lymph+	0.40
BCT/Lymph- vs Mastectomy/Lymph+	0.01
Mastectomy/Lymph- vs BCT/Lymph+	0.95
Mastectomy/Lymph- vs Mastectomy/Lymph+	0.02
BCT/Lymph+ vs Mastectomy/Lymph+	0.10

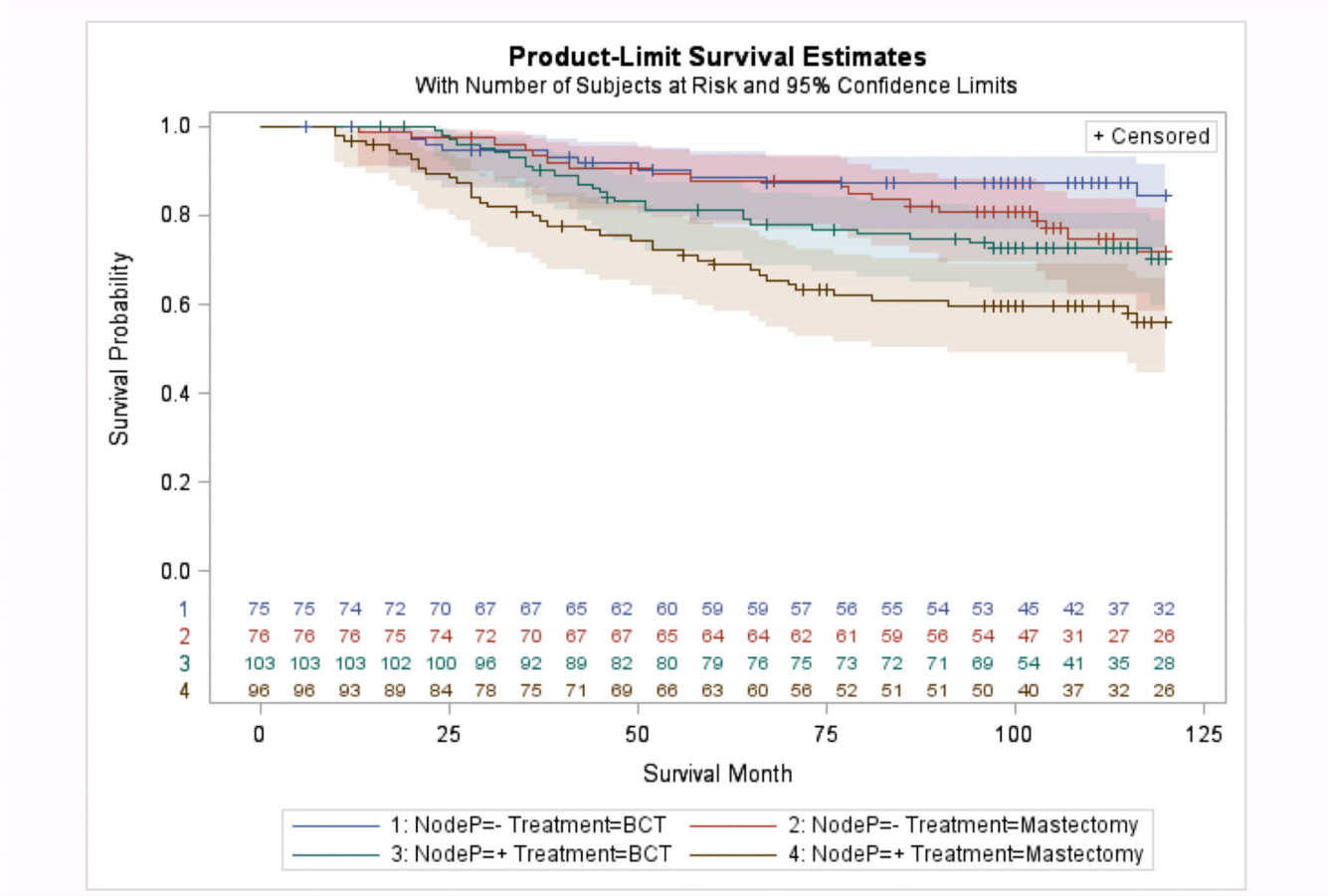

Figure 2.

Breast cancer death-specific survival rate for breast cancers treated with chemotherapy followed by breast-conserving therapy (lumpectomy plus radiation) or mastectomy without radiation, with and without lymph node involvement --Matched Pair Samples.

Table 1.

Baseline Characteristics for Female Breast Cancer Patients with Chemotherapy Followed by Surgery, New Jersey 1998–2003

Characteristics	BCT[a] (n=276) Freq (%)	Mastectomy[b] (n=442) Freq (%)	P-value
Age			0.08
24–39	41 (14.9)	47 (10.6)	
40–54	124 (44.9)	189 (42.8)	
55–64	74 (26.8)	113 (25.6)	
65–74	26 (9.4)	61 (13.8)	
75+	11 (4.0)	32 (7.2)	
Race			0.14
White	231 (83.7)	346 (78.3)	
Black	31 (11.2)	73 (16.5)	
Other	14 (5.1)	23 (5.2)	
Poverty			0.34
0% - <5%	149 (54.0)	225 (50.9)	
5% - <10%	62 (22.5)	87 (19.7)	
10% - <20%	43 (15.6)	74 (16.7)	
20% – 100%	21 (7.6)	53 (12.0)	
Unknown	1 (0.4)	3 (0.7)	
Health Insurance			0.07
Private/Medicare	209 (75.7)	340 (76.9)	
Uninsured/Medicaid	25 (9.1)	56 (12.7)	
Unknown	42 (15.2)	46 (10.4)	
Summary Stage			<0.0001*
Local	137 (49.6)	87 (19.7)	
Regional	128 (46.4)	334 (75.6)	
Unknown	11 (4.0)	21 (4.8)	
Lymph Node Involvements			<0.0001*
No lymph node involvement	130 (47.1)	85 (19.2)	
Positive lymph nodes	104 (37.7)	244 (55.2)	
Unknown	42 (15.2)	113 (25.6)	
Estrogen Receptor Assay			
Negative	56 (20.3)	112 (25.3)	0.23
Positive	129 (46.7)	183 (41.4)	
Unknown	91 (33.0)	147 (33.3)	
Progesterone Receptor Assay			0.14
Negative	77 (27.9)	151 (34.2)	
Positive	106 (38.4)	143 (32.4)	

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Characteristics	BCT[a] (n=276) Freq (%)	Mastectomy[b] (n=442) Freq (%)	P-value
Unknown	93 (33.7)	148 (33.5)	

[a]BCT (breast-conserving therapy) includes patients with lumpectomy and radiation.

[b]Mastectomy includes patients with mastectomy and no radiation.

*= statistically significant by chi-square

Table 2:

Characteristics of the Propensity Sore Matched Samples for Patients who underwent Chemotherapy Followed by Breast-Conserving Therapy (lumpectomy plus radiation) or Mastectomy (without radiation)

Characteristics	BCT[a] (n=220) Freq (%)	Mastectomy[b] (n=220) Freq (%)	P-value
Age			0.37
24–39	27 (12.3)	36 (16.4)	
40–54	105 (47.7)	96 (43.6)	
55–64	58 (26.4)	51 (23.2)	
65–74	22 (10.0)	22 (10.0)	
75+	8 (3.6)	15 (6.8)	
Race			0.71
White	180 (81.8)	174 (79.1)	
Black	28 (12.7)	34 (15.5)	
Other	12 (5.5)	12 (5.5)	
Poverty			0.84
0% - <5%	113 (51.4)	114 (51.8)	
5% - <10%	52 (23.6)	44 (20.0)	
10% - <20%	34 (15.5)	36 (16.4)	
20% – 100%	20 (9.1)	24 (10.9)	
Unknown	1 (0.5)	2 (0.9)	
Health Insurance			0.08
Private/Medicare	167 (75.9)	164 (74.5)	
Uninsured/Medicaid	20 (9.1)	33 (15.0)	
Unknown	33 (15.0)	23 (10.5)	
Summary Stage			0.82
Local	81 (36.8)	85 (38.6)	
Regional	128 (58.2)	122 (55.5)	
Unknown	11 (5.0)	13 (5.9)	
Lymph Node Involvements			0.72
No lymph node involvement	75 (34.1)	76 (34.5)	
Positive lymph nodes	103 (46.8)	96 (43.6)	
Unknown	42 (19.1)	48 (21.8)	
Estrogen Receptor Assay			0.04*
Negative	51 (23.2)	36 (16.4)	
Positive	107 (48.6)	99 (45.0)	
Unknown	62 (28.2)	85 (38.6)	
Progesterone Receptor Assay			0.02*
Negative	67 (30.5)	45 (20.5)	
Positive	89 (40.5)	89 (40.5)	

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Characteristics	BCT[a] (n=220) Freq (%)	Mastectomy[b] (n=220) Freq (%)	P-value
Unknown	64 (29.1)	86 (39.1)	

[a]BCT (breast-conserving therapy) includes patients with lumpectomy and radiation

[b]Mastectomy includes patients with mastectomy and no radiation.

*= statistically significant by chi-square