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Breast Conservation Versus Mastectomy for T3 Primaries (>5 cm): A Review of 5,685 Medicare Patients

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Abstract

Introduction—Although breast conservation therapy (BCT) is standard for breast cancer treatment, tumors >5 cm were excluded from clinical trials. Yet, only a few small retrospective series compare this to mastectomy for tumors >5 cm. This study was performed to determine if survival is equivalent for BCT versus mastectomy, using a large national dataset.

Methods—SEER-Medicare linked cases were identified for patients ages ≥66 years undergoing breast conservation for invasive noninflammatory, nonmetastatic breast cancer between 1992 and 2009. Propensity score-based adjustment was used to account for demographics, tumor and treatment factors.

Results—5,685 patients with tumors >5.0 cm underwent breast surgery, with 15.6% having breast conservation. Mean ages and tumor size were similar. Predictors of BCT included neoadjuvant chemotherapy and postoperative radiotherapy use, higher income, breast cancer as first malignancy, and higher Charlson Comorbidity Index. Predictors of mastectomy included younger age, non-ductal histology, higher grade, numbers of lymph nodes examined and positive, stage III disease, postoperative chemotherapy use, and region of the country. Adjusted overall and breast cancer-specific survival were not different between BCT and mastectomy (HR 0.934, 95% CI 0.791–1.103, p=0.419 for overall survival; sHR 1.042, 95% CI 0.793–1.369, p=0.769 for breast cancer specific survival), with each improving over time. Median follow up was 7.0 y.

Conclusion—For Medicare patients with tumors >5 cm, survival is similar between breast conservation and mastectomy, as for smaller primaries. Despite exclusion from randomized trials, breast conservation may remain an option for larger tumors, when deemed clinically and cosmetically amenable to resection.

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Keywords

Breast Cancer; Mastectomy; Segmental; Breast Neoplasms/mortality/pathology/radiotherapy/*surgery; Breast-Conserving Surgery; Feasibility Studies; Survival Rate; Treatment Outcome; Clinical Practice Patterns

INTRODUCTION

Paradigmatic changes in surgical options for breast cancer have been progressive and steady over the past thirty years, including shifts from mastectomy to breast conservation therapy (BCT),[1] axillary dissection to sentinel node biopsy,[2] and an increasing use of neoadjuvant chemotherapy[3] to allow resection of unresectable disease and to downstage primaries. But while the use of BCT has increased overall, some guidelines[4] still consider tumors >5 cm a relative contraindication to breast conservation surgery and radiotherapy, based upon limited evidence.

In the initial clinical trials, recruitment of patients was limited to those having smaller tumors. Trial upper limits specified tumor sizes of 2 cm,[5] 2.5 cm,[6] 4 cm,[1, 7] and 5 cm,[8] but there have been no prospective trials permitting breast conservation for tumors above that 5 cm threshold. Although size is theoretically not felt to affect local recurrence,[9] this remains controversial. Concerns raised about such risks for larger tumors have led recent trials that incorporate breast conservation to either include very few large tumors or exclude T3 primaries completely.[10, 11]

Despite this uncertainty, published series demonstrate that breast conservation is utilized on occasion by some for tumors >5 cm in both the adjuvant and neoadjuvant setting.[12–14] The frequency of use of breast conservation for T3 tumors in the United States, however, remains unknown. This study was performed in order to assess the patterns of care and use of breast conservation for T3 tumors in the United States Medicare population, and to determine the relative survival between the two surgical options to suggest whether size >5 cm should remain a relative contraindication to BCT.

METHODS

Data originate from the Surveillance, Epidemiology and End Results (SEER) – Medicare linked dataset, with approval from the National Cancer Institute, and our Institutional Review Board. Patients were included if they were ≥66 years of age (to ensure they would have at least one year of follow up), likely to have claims from 1 year before the SEER diagnosis date, and had nonmetastatic invasive breast cancer. Patients were excluded if they were enrolled in an HMO (as such claims are often incomplete), did not have Medicare parts A and B, had a prior breast cancer, had inflammatory carcinoma, and had a tumor ≤5 cm. The SEER AJCC T stage variable has less missing data than the size variable, so T3 designation was utilized to exclude tumors ≤5 cm, and size used when T stage was missing or unavailable. Extent of disease codes were used to exclude tumors invading skin and chest wall. Patients were not excluded if they had a non-breast malignancy during their lifetime.

Age at diagnosis, year of diagnosis, malignancy number, tumor size, histology, AJCC stage, number of nodes examined and number positive, education, marital status, income, region of the country, metropolitan setting, and grade, were derived from SEER data. Gender, Elixhauser score, Charlson comorbidity index, and use of chemotherapy and radiotherapy were derived from Medicare claims data. Race was predominantly derived from Medicare claims, but supplemented with SEER data if Medicare data were missing. SEER data were used for the type of surgery (mastectomy vs BCT), with Medicare claims surgery type used when the SEER surgery type was missing.

Registries were combined to comply with SEER-Medicare limitations on reporting individual registry data. Patients having chemotherapy preoperatively were separated from those having chemotherapy postoperatively, and the rare patients having both types of claims (0.3%) were classified with the neoadjuvant group. Patients having radiotherapy whose claims were only preoperative were excluded. Trends for BCT were performed on the cohort without excluding those having missing covariate data (n=5,922) to maximize accuracy in the raw rates of BCT performance.

We used T-tests and chi-squared tests to compare unadjusted differences. We used a multiple logistic regression to investigate the predictors of breast conservation therapy. To investigate differences between those treated with breast conservation therapy versus mastectomy, we used propensity score adjustment via inverse probability of treatment weighting.[15] We used propensity score-based weights in a Cox proportional hazards regression to examine adjusted overall survival differences, and used the weights in a Fine and Gray competing risks proportional hazards regression[16] to investigate breast cancer-specific mortality.

Heuristically, while the hazard ratio is a measure of the overall survival rate, the subdistribution hazard ratio is a measure of the cumulative incidence rate for cause-specific mortality.[16] The distinction between overall survival curves and cumulative incidence curves is that overall survival curves necessarily fall from 100% to 0% (i.e. complete mortality over time), while cumulative incidence curves generally increase from 0% to some value that is less than 100% (i.e. some people die from other causes before having the event of interest).

We used the weights to estimate adjusted overall survival,[17] adjusting for factors in Tables 1 and 2, and breast cancer-specific cumulative incidence curves. Median follow up time was determined by the method of Schemper et al.[18] In order to investigate temporal trends, we used simple logistic regressions of BCT use or neoadjuvant therapy use and a simple linear regression for tumor size. We added year to these models via an untransformed linear term. STATA version 13 (Statacorp, College Station, TX) was used for analyses. P-values less than 0.05 were used to declare statistical significance.

RESULTS

There were 5,922 patients with treatment data after all exclusion criteria (Figure 1), among whom 887 patients (15.6%) underwent breast conservation between 1992 and 2009. Patient

and tumor characteristics are listed in Table 1 for those with complete covariate data (n=5,685, see Figure 1). Overall, patients averaged 77.4 years (standard deviation [SD]=7.5), and had a mean and median tumor size of 7.6 cm (SD=5.1 cm) and 6.5 cm, respectively. The mean Charlson Comorbidity index was 0.58 (SD=1.02), and Elixhauser score 1.54 (SD=3.92). The entire cohort had an average of 10.7 (SD=8.3) lymph nodes examined, with significantly fewer examined in the breast conservation subgroup, while the average number of nodes positive was 3.7 (SD=5.7) overall, with more positive nodes found in the mastectomy subset. Among patients having mastectomy, 33.3% first had a lumpectomy.

The largest coefficient predictor of breast conservation therapy use was the use of neoadjuvant chemotherapy (Odds ratio [OR] 3.40; 95% CI 2.46 – 4.70, p<0.001), while the largest coefficient predictor of mastectomy use was stage III disease (OR 0.39; 95% CI 0.31 – 0.48, p<0.001). Predictors of breast conservation included use of neoadjuvant chemotherapy and postoperative radiotherapy, higher income, a history of a prior non-breast malignancy, and higher Charlson comorbidity index. Factors associated with greater use of mastectomy included younger age at diagnosis, Asian race, lobular or other non-ductal histology, higher grade, greater numbers of lymph nodes examined and positive, AJCC stage III disease, postoperative chemotherapy use, treatment in the midwest, west and south (relative to the northeast), and treatment in a less urban/rural metropolitan area. The multiple logistic regression for BCT is listed in Table 2.

The unadjusted use of breast conservation for tumors >5 cm increased over time, (OR=1.02 per year, 95% CI 1.01–1.04 p=0.003) from 10.4% to 18.6% with spikes in 1997 at 19.7% and 2005 at 19.6% (Figure 2). During the same period, the use of neoadjuvant chemotherapy decreased from 6.5% to 3.0% (OR=0.95 per year, 95% CI 0.92– 0.97, p<0.001), while pathologic tumor size did not change (average change of 0.009 cm/year, 95% CI −.02 to 0.04 cm/year p=0.54). In the adjusted cohorts, ER and PR positivity were similar between groups. ER positivity occurred in 64.3% of the mastectomy group and 66.6% of the BCT group (p = 0.466), while PR positivity occurred in 49.9% of the mastectomy group and 51.6% of the BCT group (p = 0.581).

Overall survival (OS) and disease-specific survival (DSS) for breast conservation versus mastectomy were not different. Adjusted hazard ratio (HR) among those with complete covariate data for overall survival for breast conservation versus mastectomy is HR 0.934 (95% CI 0.791–1.103, p=0.419) for overall survival. Subhazard ratio for adjusted disease-specific mortality was 1.042 (95%CI 0.793–1.369, p=0.769). Survival curves are shown in Figure 2. OS improved over time (HR=0.975 per year, 95% CI 0.955–0.995, p=0.016) for all cases, but there was no evidence that the rate of improvement over time differed between BCT and mastectomy treated cases (p=0.82 for comparison of time trends between treatment groups using interaction term). DSS demonstrated a similar improvement, and the result did not reach significance (sHR=0.969 per year, 95% CI 0.937–1.001, p=0.060, p=0.61 for interaction term).

DISCUSSION

BCT has been standard of care for decades, and the subject of multiple prospective trials for tumors ≤5 cm. Although results from clinical trials are typically only applied to patients fitting the entry criteria used by the trial, BCT has become so prevalent and arguably, so successful, that practitioners have expanded the use of lumpectomy with radiotherapy beyond the clinical setting evaluated by those randomized trials. For example, no level I evidence demonstrates the safety of BCT for DCIS, but the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) meta-analysis data and modeling data support its use and it is now prevalent. Trials from the 1970s and 1980s evaluated women whose tumors were unifocal,[1, 19] but multifocality is no longer a relative contraindication. For tumors >5 cm, however, we have little data, as the trials excluded these tumors, and so even the large Oxford Overview cannot provide guidance for this subset of patients.

We have demonstrated that for tumors >5 cm, breast conservation provides overall and breast cancer-specific survival equivalent to mastectomy, confirming the safety of this approach. We have also noted that while OS and DSS improved for both BCT and Mastectomy for tumors >5 cm over time, the OS and DSS equivalence between the two treatments remained the same throughout the period of study. Although there is no clinical trial evaluating BCT for large tumors, it is highly unlikely that another breast conservation trial will ever be performed because of resource limitations and the small proportion of women having T3 primaries whose relative breast size may permit BCT. Consequently, we must rely upon retrospective data via large datasets to determine whether this approach appears safe. This study is consistent with the few smaller retrospective series that suggest that size >5 cm should not remain a relative contraindication to breast conservation.[20, 21]

This study has also found that the use of breast conservation for T3 tumors in the Medicare population has been steadily increasing since 1992, but even as of 2009, its use remains low with only about one in five patients >5 cm being treated with breast conservation. The reasons for the low use of BCT in this population remains uncertain. While patient choice may be reflected in these data, the most likely explanation is that few patients are eligible to undergo BCT due to large tumor size relative to breast size based upon the judgement of the surgeon. Adoption may also be limited by surgeons because of the paucity of data demonstrating its safety, and the fact that there remains a continued designation in current guidelines that size >5 cm is a relative relative contraindication to BCT.[4]

The use of BCT in T3 tumors is increasing however, and this may be multifactorial. One possibility is that this is a reflection of rising obesity rates[22] with consequent enlargement of breast size on average, making resection easier. This is suggested by our finding that while BCT use increased, there was a concurrent decrease in the use of neoadjuvant chemotherapy in these patients while tumor sizes did not change. These findings could also be explained by increasing surgeon comfort or greater experience in using BCT for larger tumor sizes. Patient desires may also be changing.

Neither SEER-Medicare data, nor other large datasets such as the National Cancer Database can determine rates of local recurrence, but the rates in the original breast conservation trials

for smaller tumors varied widely,[23] with odds ratios ranging from 0.728 to 3.365.[24] Margin status is also not available in the SEER-Medicare dataset, but until recently there was no consensus on appropriate margin widths. Moreover, some of the original clinical trials demonstrating equivalency between BCT and mastectomy did not even require negative margins.[25, 26] Because a link between local recurrence and survival has now been established via the EBCTCG (noting that for every four recurrences prevented, one woman's lifespan is extended at 15 years[27]) the similarities in breast cancer-specific and overall survival seen here suggest that if any local recurrence difference for this group exists, it is small, consistent with the original trials.

The exclusion of larger tumors in the prospective series was, presumably, out of concern for safety and the feasibility of completely resecting these lesions. Larger tumors confer a less favorable prognosis, and may be harder to resect with equivalent cosmesis, but the issue in question is not whether patients can be made to undergo breast conservation when their tumor is too large and/or their breast size is too small. The concern is whether those patients deemed cosmetically amenable to resection can safely undergo the procedure without a compromise in outcome relative to mastectomy. In a small series evaluating 20 patients undergoing BCT for T2 and T3 tumors measuring up to 6.5 cm, outcomes were identical while cosmesis was judged by patients to be similar to that performed for smaller tumors, underscoring the importance of patient selection.[21]

One issue of pertinence for local resection is the incidence of multifocality and multicentricity (MF/MC). While some data suggests that MF/MC increases with T stage,[28] this is controversial as there is little biologic reason to think that tumors >5 cm behave differently than those ≤5 cm.[9] Other data note that larger tumors are not more likely to be multifocal[29] and that, conversely, the number of foci does not predict tumor size.[30] Estimates of the incidence of MF/MC in breast cancer varies widely upwards of 6%.[28] Consistently, however, data do not demonstrate an increase in relapse among tumors exihibiting MF/MC as versus unifocality,[29, 31, 32] and when adjusting for other prognostic factors, MF/MC does not correlate with survival.[28] This issue remains a concern though, as our detection of MC/MF disease has improved with advances in imaging such as MRI[33] and there is a greater use of mastectomy in some series because of our compulsion to resect all such foci visualized.[34]

The ability to provide BCT as an option for patients also has important psychological considerations. Prior prospective data have demonstrated a correlation between BCT and improved quality of life with respect to body image and treatment satisfaction, while noting no increase in the fear of recurrence.[35] Breast conservation has become a national standard for the treatment of early breast cancer,[36] and our data reinforces the notion that the option should be provided to all those clinically amenable to local resection.

In conclusion, BCT is safe for tumors >5 cm in the Medicare population as demonstrated by similar overall and disease-specific survival as versus mastectomy. The increasing trend in its use is encouraging, as it suggests that more women are being given surgical options previously considered to be contraindicated. Although a prospective trial would be ideal, we do not anticipate resources to be allocated to another such trial. We therefore recommend

that size no longer be considered a relative contraindication in this subgroup of patients, when breast size can accommodate such a resection.

Acknowledgments

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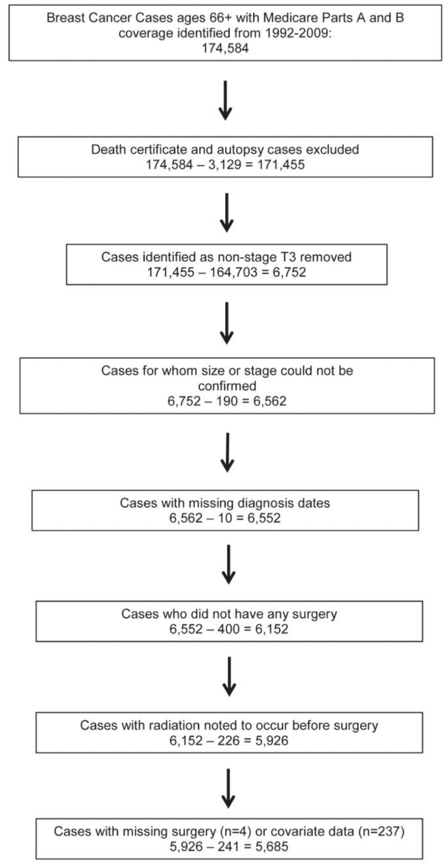

Figure 1.
Exclusion criteria.

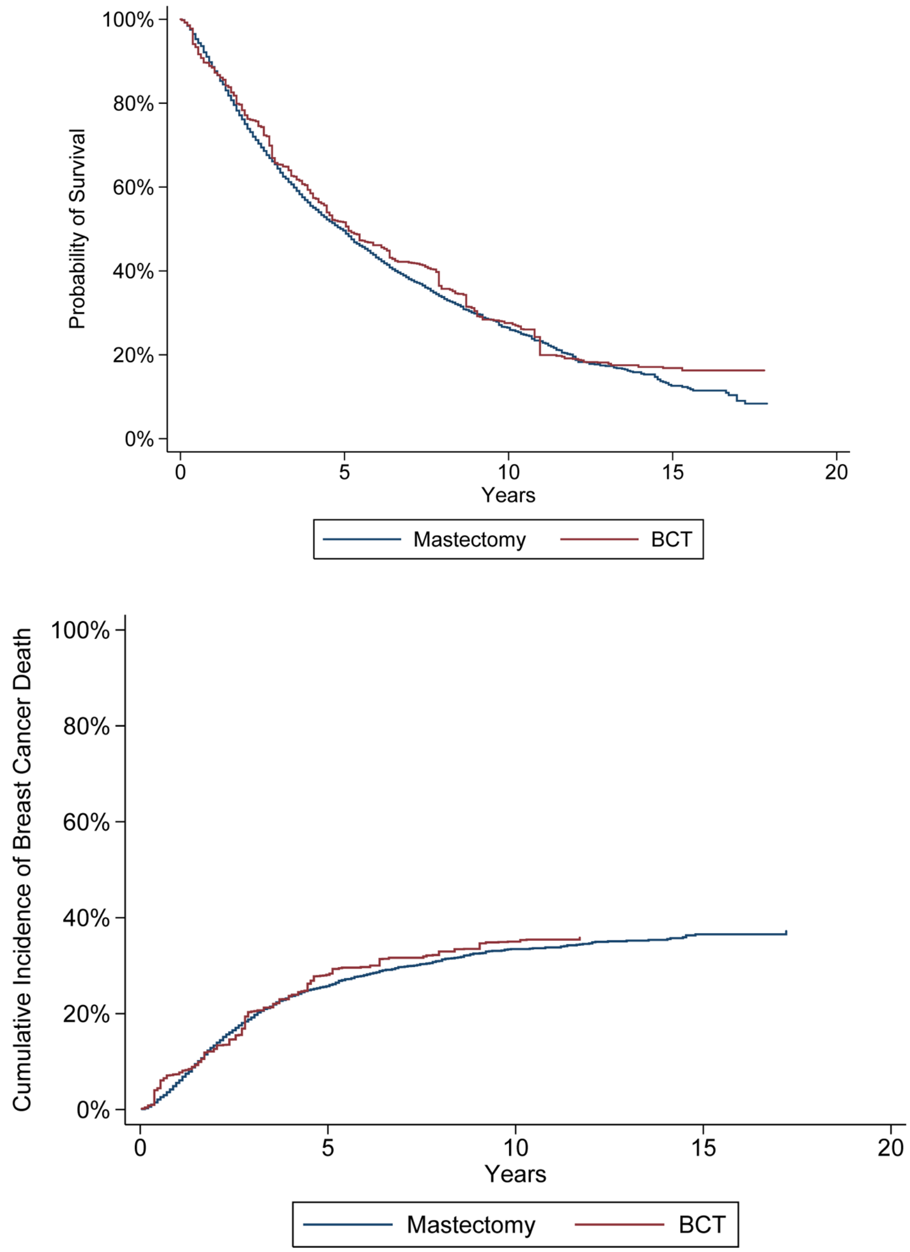

Figure 2.

Survival comparisons of breast conservation versus mastectomy. Panel A: Adjusted overall survival. HR for breast conservation = 0.934, 95% CI 0.791–1.110, $p = 0.419$. Panel B: Breast Cancer-specific mortality. HR for breast conservation = 1.042, 95% CI 0.792–1.369, $p = 0.769$.

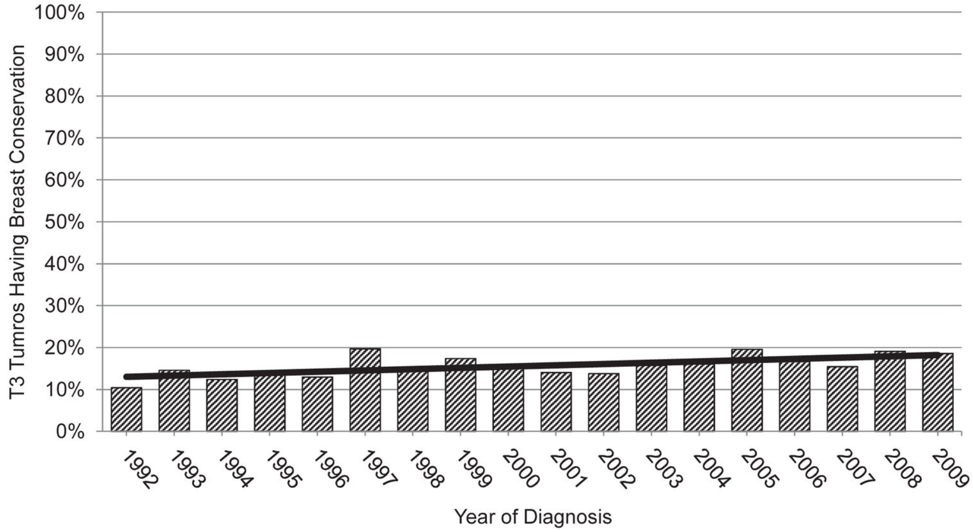

Figure 3.

Unadjusted use of breast conservation for T3 tumors over time. The *p* for trend (increasing) = 0.003.

Table 1

Characteristics by surgical treatment. Numbers shown (column %) unless otherwise indicated.

Characteristic	Patients Having Breast Conservation (*n*=887)	Patients Having Mastectomy (*n*=4,798)	*p*
Age at Diagnosis (Mean ± SD*)Δ	77.62 ± 7.71	77.42 ± 7.51	0.471
66–74	342 (38.56)	1,875 (39.08)	0.711
75–84	363 (40.92)	2,016 (42.02)	
85–94	166 (18.71)	821 (17.11)	
95+	16 (1.80)	86 (1.79)	
Gender			0.232
Male	§	40 (0.83)	
Female	§	4,758 (99.17)	
Race			<0.001
White	760 (85.68)	4,026 (83.91)	
Black	94 (10.60)	558 (11.63)	
Asian	§	84 (1.75)	
Hispanic	§	51 (1.06)	
Other/Unknown	14 (1.58)	79 (1.65)	
Elixhauser Score (Mean ± SD*)	1.78 ± 4.06	1.49 ± 3.89	0.049
Charlson Comorbidity Score (Mean±SD*)	0.65 ± 1.07	0.56 ± 1.01	0.004
Marital Status			0.118
Not married	568 (64.04)	3,202 (66.74)	
Married	319 (35.96)	1,596 (33.26)	
Education**	18.49 ± 13.69	19.90 ± 13.48	0.004
Income by census tract (Mean ± SD*)	52,481.34 ± 26,868.1	47,103.97 ± 23,014.41	<0.001
Region of the Country‡			<0.001
Northeast	244 (27.51)	912 (19.01)	
Midwest	128 (14.43)	887 (18.49)	
West	374 (42.16)	2,010 (41.89)	
South	141 (15.90)	989 (20.61)	
Urban Setting¶			<0.001
Big Metropolitan	563 (63.47)	2,741 (57.13)	
Metropolitan	232 (26.16)	1,301 (27.12)	
Urban	47 (5.30)	260 (5.42)	
Less Urban/Rural	45 (5.07)	496 (10.34)	
Year of Diagnosis (Mean ± SD*)	2002 ± 5	2002 ± 5	0.003
Number of Cancer† (Mean ± SD*)	1.08 ± 0.32	1.06 ± 0.26	0.011
Size (cm, Mean ± SD*)Δ	7.86 ± 7.05	7.50 ± 4.69	0.055

Characteristic	Patients Having Breast Conservation (*n*=887)	Patients Having Mastectomy (*n*=4,798)	*p*
5.1–7.0 cm	612 (69.00)	3,153 (65.71)	0.043
7.1–10.0 cm	201 (22.66)	1,279 (26.66)	
10.1+	74 (8.34)	366 (7.63)	
Histology			<0.001
Ductal	682 (76.89)	3,335 (69.51)	
Lobular	148 (16.69)	1,159 (24.16)	
Other/Unknown	57 (6.43)	304 (5.34)	
Grade			<0.001
Well differentiated	605 (10.64)	442 (9.21)	
Moderately differentiated	1,959 (34.46)	1,663 (34.66)	
Poorly differentiated	2,248 (39.54)	1,970 (41.06)	
Undifferentiated	142 (2.50)	120 (2.50)	
Not determined/Not stated	731 (12.86)	603 (12.57)	
Nodes Examined (Mean ± SD*)	5.27 ± 6.95	11.76 ± 8.08	<0.001
Nodes Positive (Mean ± SD*)	1.03 ± 2.96	4.15 ± 5.95	<0.001
AJCC Stage			<0.001
Stage II	612 (69.00)	1,570 (32.72)	
Stage III	275 (31.00)	3,228 (67.28)	
Neoadjuvant Chemotherapy			<0.001
Not administered	786 (88.61)	4,694 (97.83)	
Administered	101 (11.39)	104 (2.17)	
Adjuvant Chemotherapy			<0.001
Not administered	694 (78.24)	2,996 (62.44)	
Administered	193 (21.76)	1,802 (37.56)	
Radiotherapy			0.004
Not administered	435 (49.04)	2,607 (54.34)	
Administered	452 (50.96)	2,191 (45.66)	

[*] SD = Standard Deviation

[Δ] Age and size analyses are shown here both as continuous and categorical variables to illustrate cohort compositions.

[**] Education represents the percentage of people in a zip code from census data having less than 12 years of education.

[‡] Region groupings: Northeast = Connecticut and New Jersey registries; South = Atlanta, Rural Georgia, Kentucky, and Louisiana registries; Midwest = Detroit and Iowa registries; West = Hawaii, New Mexico, Seattle, Utah, and California registries

[¶] Setting definitions: Large metropolitan = counties of metropolitan areas of ≥1,000,000; metropolitan = counties in metropolitan areas of <250,000–1,000,000; urban = urban population of ≥20,000 adjacent or nonadjacent to a metropolitan area; less urban = urban population of 2,500–19,999 adjacent or nonadjacent to a metropolitan area; rural = completely rural or <2,500 urban population, adjacent or nonadjacent to a metropolitan area.

[†] The number of the cancer, if patients had more than one.

[§] As per NCI SEER-Medicare requirements, cells containing fewer than 11 individuals and any cells making them calculable have been censored.

Table 2

Predictors of breast conservation.

Characteristic	Odds Ratio	95% CI	*p*
Per 10y increase in age	0.83	0.93 – 0.94	0.004
Gender			
Male	Referent	Referent	—
Female	2.72	0.89 – 8.25	0.078
Race			
White	Referent	Referent	—
Black	0.97	0.73 – 1.29	0.853
Asian	0.47	0.23 – 0.97	0.040
Hispanic	1.14	0.51 – 2.55	0.747
Other/Unknown	0.98	0.51 – 1.88	0.948
Elixhauser Score	0.99	0.97 – 1.02	0.574
Charlson Comorbidity Score	1.12	1.02 – 1.24	0.023
Marital Status			
Not married	Referent	Referent	—
Married	1.12	0.94 – 1.35	0.216
Education[‡]	1.03	0.95 – 1.12	0.469
Income[*]	1.07	1.02 – 1.12	0.003
Region of the Country[**]			
Northeast	Referent	Referent	—
Midwest	0.67	0.51 – 0.88	0.004
West	0.78	0.64 – 0.97	0.023
South	0.69	0.53 – 0.90	0.007
Urban Setting[¶]			
Big Metropolitan	Referent	Referent	—
Metropolitan	0.90	0.74 – 1.09	0.288
Urban	0.85	0.58 – 1.24	0.404
Less Urban/Rural	0.59	0.41 – 0.86	0.006
Year of Diagnosis[§]	1.04	0.86 – 1.25	0.718
First Cancer[†]	1.38	1.04 – 1.83	0.025
Size (cm)	1.00	0.99 – 1.02	0.675
Histology			
Ductal	Referent	Referent	—
Lobular	0.49	0.39 – 0.61	<0.001
Other/Unknown	0.61	0.44 – 0.85	0.004
Grade			
Well differentiated	Referent	Referent	—

Characteristic	Odds Ratio	95% CI	*p*
Moderately differentiated	0.62	0.48 – 0.79	<0.001
Poorly differentiated	0.57	0.44 – 0.73	<0.001
Undifferentiated	0.68	0.39 – 1.19	0.181
Not determined/Not stated	0.84	0.61 – 1.14	0.265
Number of Nodes Examined	0.91	0.89 – 0.92	<0.001
Number of Nodes Positive	0.96	0.93 – 0.99	0.018
AJCC Stage			
Stage II	Referent	Referent	—
Stage III	0.39	0.31 – 0.48	<0.001
Neoadjuvant Chemotherapy			
Not administered	Referent	Referent	—
Administered	3.40	2.46 – 4.70	<0.001
Adjuvant Chemotherapy			
Not administered	Referent	Referent	—
Administered	0.61	0.49– 0.76	<0.001
Radiotherapy			
Not administered	Referent	Referent	—
Administered	2.84	2.34 – 3.44	<0.001

[‡]Odds ratio represents each incremental 10% increase in ZIP code residents having less than 12 years of education.

[*]Odds ratio for every $10,000 increase in median income

[**]Region groupings: Northeast = Connecticut and New Jersey registries; South = Atlanta, Rural Georgia, Kentucky, and Louisiana registries; Midwest = Detroit and Iowa registries; West = Hawaii, New Mexico, Seattle, Utah, and California registries

[¶]Setting definitions: Large metropolitan = counties of metropolitan areas of ≥1,000,000; metropolitan = counties in metropolitan areas of <250,000–1,000,000; urban = urban population of ≥20,000 adjacent or nonadjacent to a metropolitan area; less urban = urban population of 2,500–19,999 adjacent or nonadjacent to a metropolitan area; rural = completely rural or <2,500 urban population, adjacent or nonadjacent to a metropolitan area.

[§]Odds ratio for a 10-year difference

[†]The number of the cancer, if patients had more than one.