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Long-term Patient-Reported Outcomes in Older Breast Cancer Survivors: A Population-Based Survey Study

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Abstract

Purpose—For older women with breast cancer, local therapy options may include lumpectomy plus whole-breast irradiation (Lump + WBI), lumpectomy plus brachytherapy (Lump + Brachy), lumpectomy alone (Lump alone), mastectomy without radiation therapy (Mast alone), and mastectomy plus radiation therapy (Mast + RT). We surveyed a population-based cohort of older breast cancer survivors to assess the association of local therapy with long-term quality-of-life outcomes.

Methods and Materials—We used nationally comprehensive Medicare claims to identify women aged ≥ 67 years in whom nonmetastatic breast cancer was diagnosed in 2009, who were treated with 1 of the 5 aforementioned treatment options, and who were still alive in 2015. From

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this cohort, 1650 patients (330 patients per treatment) were randomly selected. A survey that included the CanSORT (Cancer Surveillance and Outcomes Research Team) Satisfaction with Breast Cosmetic Outcome, BREAST-Q, Decisional Regret Scale, and EQ-5D-3L was mailed to potential participants. We used multivariable linear regression to assess associations between local therapy and outcomes after adjusting for patient, disease, and treatment covariates.

Results—Among the 489 women who returned the surveys (30% response rate), the median age at diagnosis was 72 years (range, 67–87 years). The interval from diagnosis to survey completion was approximately 6 years for all patients. Compared with Lump + WBI (adjusted score, 3.40), the CanSORT cosmetic satisfaction scores were higher for Lump + Brachy (score, 3.77; $P = .007$) and Lump alone (score, 3.80; $P = .04$) and lower for Mast + RT (score, 3.01; $P = .006$). Similar trends were seen for BREAST-Q cosmetic satisfaction. BREAST-Q psychosocial, sexual, and physical well-being and EQ-5D-3L global health status tended to be better in patients treated with less irradiation and less surgery. BREAST-Q adverse radiation effects were worse for Lump + WBI compared with Lump + Brachy. Decisional regret regarding surgery and radiation therapy did not differ across groups. Compared with patients treated with Lump + WBI, patients treated with Lump + Brachy and Lump alone reported slightly higher rates of in-breast recurrence (excess risk of 5.8% and 6.4%, respectively; $P = .01$).

Conclusions—In this nationally diverse cohort, less irradiation and less surgery were associated with better long-term quality-of-life outcomes. However, patient regret regarding surgery and radiation therapy was similar across all groups.

Introduction

Over 100,000 of the nearly 250,000 new breast cancer cases per year in the United States are diagnosed in women older than 65 years, and this number is projected to increase substantially by the year 2030 (1). Older women with breast cancer face unique challenges, including physiological limitations (2, 3) and comorbid illness (4). On the other hand, tumor biology in older women tends to be less aggressive (5, 6), and randomized evidence has demonstrated a low risk of local recurrence in older women with small, estrogen receptor—positive tumors after lumpectomy and endocrine therapy alone (7, 8). Such evidence has led to a proliferation of acceptable guideline-concordant local therapy options over the past few decades. Current options include lumpectomy plus whole-breast irradiation (Lump + WBI) (9, 10), lumpectomy plus brachytherapy (Lump + Brachy) (11), lumpectomy plus endocrine therapy alone (Lump alone) (7, 8), mastectomy alone (Mast alone) (9), and when clinically indicated, mastectomy plus radiation therapy (Mast + RT) (12, 13).

Each of these options has its advantages and drawbacks in terms of local control, side effects, and convenience. However, little is known about long-term patient-reported quality-of-life (QOL) outcomes among older women following treatment with each of these strategies. Such data would be helpful when counseling older patients about their options so that they will be able to select a treatment that will optimize their long-term health outcomes. To address this gap in knowledge, we conducted a population-based survey of Medicare beneficiaries treated with 1 of these 5 local therapy strategies to assess the association between treatment choice and long-term QOL outcomes.

Methods and Materials

Survey development and pilot testing

We developed a paper survey to collect baseline patient information and patient-reported outcomes (PROs) using validated instruments and piloted the survey in 10 patients at our institution. Cognitive interviews assessed the length and clarity of the survey (14).

Cohort selection

We applied a validated algorithm to nationally comprehensive Medicare claims to identify women aged 67 years in whom nonmetastatic breast cancer was diagnosed in 2009 (N = 42,735) (15, 16). From this group, we included only patients who were treated with 1 of the 5 local therapy strategies of interest, who were alive as of May 2015, and who had continuous fee-for-service Medicare Part A and B coverage between diagnosis and the end of 2011 (n = 26,542). We excluded patients who had any other cancer diagnosis after the breast cancer diagnosis. The remaining 26,069 patients comprised the cohort from which potential survey participants were selected (Table E1; available online at www.redjournal.org).

Determination of treatment

We used Current Procedural Terminology and *International Classification of Diseases, Ninth Revision* procedure codes to classify surgery and radiation therapy within 1 year of diagnosis (Table E2; available online at www.redjournal.org). We defined “Lump + WBI” as a lumpectomy followed by 15 unique external beam radiation treatments and no brachytherapy within 1 year of diagnosis (and without a mastectomy between lumpectomy and whole-breast irradiation [WBI]). We defined “Lump + Brachy” as a lumpectomy followed by brachytherapy (specifically high-dose-rate brachytherapy most commonly delivered with a single-entry catheter; intraoperative radiation therapy and electronic brachytherapy were not included), with no mastectomy or external beam radiation therapy within 1 year of diagnosis. We defined “Lump alone” as a lumpectomy plus a filled prescription for endocrine therapy, with no mastectomy within 1 year of diagnosis. We defined “Mast alone” as a mastectomy without any radiation therapy within 1 year of diagnosis. Finally, we defined “Mast + RT” as a mastectomy followed by 15 unique external beam radiation treatments within 1 year of diagnosis. Patients who did not fit into any of these groups were excluded (Table E1; available online at www.redjournal.org) because they did not appear to receive guideline-concordant local therapy.

Sampling strategy

Of the patients, 49% (n = 12,731) received local therapy with Lump + WBI, which is consistent with other large database studies (17, 18). Lump + WBI therefore served as the referent group for all analyses. We used a power calculation to determine that a minimum required sample size of 250 per treatment group should achieve 80% power to detect an effect size of 0.31 points on a 5-point Likert scale, a threshold that was based on the published distributions for the CanSORT (Cancer Surveillance and Outcomes Research Team) Satisfaction with Breast Cosmetic Outcome scale. Assuming a 75% response rate, we

chose to survey 330 patients per treatment group. First, we randomly sampled 330 patients treated with Lump + WBI. We then used probability proportional to size sampling without replacement to select 330 patients treated with each of the remaining 4 local therapy strategies such that the age distribution was similar to that of the Lump + WBI group.

Data collection

Following approval from our institutional review board and the Centers for Medicare & Medicaid Services (CMS), a flyer with a description of our study and an opt-out card were mailed by the CMS beneficiary contact service to 1650 patients in September 2015. Among these patients, 397 (24%) returned opt-out cards. We mailed an invitation letter, paper survey, and \$10 gift card to the remaining 1253 potential participants in November 2015. Methods as developed by Dillman (19) were used to improve response rates, with mailings continuing through January 2016. Follow-up phone calls were conducted for patients who provided their telephone numbers on initial response cards.

PRO measures

The paper survey included a section of general questions to ascertain each participant's current cancer status, including details on any breast cancer recurrence (local or distant), any subsequent mastectomy, or any second primary malignancies. We also asked about current height and weight, weight at diagnosis, bra cup size, smoking history, ethnicity, race, education, and household income.

The primary outcome was cosmetic satisfaction as measured by the CanSORT Satisfaction with Breast Cosmetic Outcome instrument (20). This instrument contains 6 items scored on a 5-point Likert scale, with a higher score indicating a higher level of satisfaction. The total score is the arithmetic mean of the 6 items.

Additional PROs were measured using the BREAST-Q instrument (21), the Decisional Regret Scale for surgery and radiation therapy (22), and the EQ-5D-3L health-related QOL instrument (23). The BREAST-Q is a validated instrument that assesses outcomes in breast cancer surgery patients. It contains multiple sections that can be administered separately or together. In our study we included the following sections: Satisfaction with Breast, Psychosocial Well-Being, Physical Well-Being, Sexual Well-Being, and Adverse Effects of Radiation, if applicable. For each section, the scores of the individual items are summed and then a Rasch transformation is used to convert the sum to a score ranging from 0 to 100. A higher score indicates a better QOL outcome.

The Decisional Regret Scale is a validated instrument that assesses regret following major treatment decisions (22); scores range from 0 (least regret) to 100 (most regret). The EQ-5D-3L health-related QOL instrument is a widely used tool that provides insight into the patient's overall QOL and permits calculation of health utilities in decision analyses (23, 24).

Statistical analyses

We compared baseline patient and demographic characteristics between different treatment groups using the χ^2 test or Fisher exact test when cell sizes were small. We compared self-reported cancer outcomes using the Fisher exact test. For each PRO, we used multivariable linear regression to evaluate the independent effect of treatment group on outcomes after controlling for covariates. Candidate covariates for all models were derived from either Medicare enrollment files (age, geographic region), Medicare claims (Charlson Comorbidity Index, axillary surgery, chemotherapy receipt), or self-report (race, body mass index, bra cup size, endocrine therapy, education level, current household income, smoking status). We included all variables in a saturated model and then used backward elimination to remove variables from the model until all remaining variables were significant at $P < .1$. Treatment group was retained in the models regardless of significance. Receipt of chemotherapy and receipt of endocrine therapy were only retained in the models when found to be significant at $P < .1$.

For the cosmetic satisfaction outcomes, we performed 2 sensitivity analyses, excluding patients with recurrence in the first and excluding mastectomy patients with reconstruction (as determined from self-report) in the second. For all outcomes, we performed sensitivity analyses that excluded the Mast + RT group, as these patients may have had more extensive disease that influenced their QOL outcomes beyond the effects of the treatment itself.

All analyses incorporated weights to adjust for differences in sample selection and nonresponse so that the results are more representative of the sample population (20). All statistical analyses were conducted in SAS (version 9; SAS Institute) with $\alpha = .05$ considered statistically significant.

Results

Patient characteristics

A total of 489 women returned surveys and endorsed a history of breast cancer or ductal carcinoma in situ in the past 10 years (30% response rate). Patient characteristics of responders and nonresponders are listed in Table E3 (available online at www.redjournal.org). Response rates varied by treatment group, age, race, Charlson Comorbidity Index, chemotherapy receipt, and geographic region ($P < .05$ for all).

Treatment was as follows: Lump + WBI in 108 patients (22%), Lump + Brachy in 103 (21%), Lump alone in 78 (16%), Mast alone in 89 (18%), and Mast + RT in 111 (23%). Of the 200 patients treated with mastectomy, 32 (16%) reported that they underwent postmastectomy breast reconstruction. The median age at diagnosis of all responders was 72 years (range, 67–87 years). The interval from diagnosis to survey was approximately 6 years for all patients. Additional patient characteristics are listed in Table 1.

Patient-reported cancer outcomes

In comparison with patients treated with Lump + WBI, the absolute excess risk of patient-reported in-breast recurrence was 5.8% higher for women treated with Lump + Brachy and

6.4% higher for women treated with Lump alone ($P = .01$). In comparison with patients treated with Lump + WBI, the absolute excess risk of subsequent mastectomy was 5.9% higher for women treated with Lump + Brachy ($P < .001$) and 0.9% lower for patients treated with Lump alone (Table 2). Absolute risks cannot be reported because of certain small cell sizes, in accordance with CMS policy.

Patient-reported cosmetic outcomes

Adjusted cosmetic satisfaction scores are summarized in Table 3. For the CanSORT score, compared with patients treated with Lump + WBI (adjusted score, 3.40), patients treated with Lump + Brachy (score, 3.77; $P = .007$) or Lump alone (score, 3.80; $P = .04$) reported greater satisfaction while patients treated with Mast + RT (score, 3.01; $P = .006$) reported less satisfaction. There was a trend toward less satisfaction with Mast alone (score, 3.11) compared with Lump + WBI, but this difference was not statistically significant ($P = .06$).

For the BREAST-Q Satisfaction with Breast outcome, compared with patients treated with Lump + WBI (adjusted score, 60.00), patients treated with Lump + Brachy (score, 66.95; $P = .03$) reported greater satisfaction while patients treated with Mast + RT (score, 50.24; $P = .001$) reported less satisfaction. There was no statistically significant difference in scores between Lump + WBI and Lump alone (score, 67.82; $P = .12$) or between Lump + WBI and Mast alone (score, 59.27; $P = .83$). The full multivariable models are presented in Table E4 (available online at www.redjournal.org).

Because patient-reported cosmetic satisfaction may be influenced by recurrence and/or reconstruction, we performed 2 sensitivity analyses, with the first excluding the 51 patients who reported breast cancer recurrence and the second excluding the 32 patients who reported undergoing reconstruction after mastectomy. Both of these analyses yielded similar results to the full cohort (Tables E5 and E6; available online at www.redjournal.org).

Patient-reported psychosocial, sexual, and physical well-being and adverse radiation effects

Adjusted scores for BREAST-Q psychosocial, sexual, and physical well-being and adverse radiation effects are presented in Table 4. For psychosocial well-being, compared with patients treated with Lump + WBI (adjusted score, 75.9), patients treated with Mast + RT (score, 64.3; $P < .001$) reported worse outcomes. For sexual well-being, compared with patients treated with Lump + WBI (adjusted score, 49.1), patients treated with Mast + RT (score, 27.2; $P < .001$) reported worse outcomes. For physical well-being, compared with Lump + WBI (adjusted score, 81.4), patients treated with Lump + Brachy (score, 86.9; $P = .02$) reported better outcomes while patients treated with Mast + RT (score, 73.0; $P < .001$) reported worse outcomes. For adverse radiation effects, compared with Lump + WBI (adjusted score, 90.4), patients treated with Lump + Brachy (score, 94.8; $P = .04$) reported better outcomes. The full multivariable models are presented in Tables E7 and E8 (available online at www.redjournal.org).

Patient-reported decisional regret and health utilities

Adjusted decisional regret scores for surgery and radiation therapy are presented in Table 5. In comparison with patients treated with Lump + WBI, there were no significant differences in decisional regret regarding surgery or radiation therapy ($P = .09$). The full multivariable models are presented in Table E9 (available online at www.redjournal.org).

Adjusted health utilities scores as measured by the EQ-5D-3L instrument are also presented in Table 5. Compared with patients treated with Lump + WBI (adjusted score, 0.86), patients treated with Mast+ RT (score, 0.78; $P = .004$) had significantly worse global health status. The full multivariable model is presented in Table E10 (available online at www.redjournal.org).

Sensitivity analyses for all outcomes excluding Mast + RT

For all PROs, sensitivity analyses excluding patients treated with Mast + RT did not yield results that were significantly different from those presented in the primary analyses (data not shown).

Discussion

In this nationally diverse cohort of breast cancer survivors, we found that, in general, long-term QOL outcomes were better with less surgery and less irradiation and that patients treated with both mastectomy and radiation therapy had significantly worse QOL outcomes in nearly every measured domain. However, among the patients who underwent initial treatment with a breast-conserving approach, the patient-reported in-breast recurrence rates were slightly higher in those treated with less irradiation (Lump + Brachy or Lump alone) compared with Lump + WBI. Despite these differences, no significant differences in decisional regret by chosen local therapy were noted. These findings are relevant to patient choices and physician counseling and could be incorporated into decision aids and formal cost-effectiveness models.

Surprisingly, little is known about the comparative impact of local therapy choices on patient QOL. In 1992 a seminal survey study of 109 breast cancer patients found that there were no significant differences in QOL, mood, and psychosocial adjustment between women treated with modified radical mastectomy and those treated with segmental mastectomy followed by radiation therapy (25). However, few population-based studies have been performed, and such studies have been limited by the duration of follow-up and failure to distinguish treatment groups in as granular a fashion as in our study (20).

The results of our study may inform how older patients with newly diagnosed early-stage breast cancer approach decisions about their local therapy. The first decision for these patients is whether they prefer mastectomy or breast conservation, 2 approaches that have been shown to offer equivalent survival in appropriately selected patients (9). We found that mastectomy alone trended toward worse cosmetic satisfaction and psychosocial well-being compared with Lump + WBI, although neither of these differences reached statistical significance ($P = .06$ for both). In an era of variable surgical trends [eg, increasing mastectomy rates among all patients with early-stage breast cancer (26) and increasing

breast-conservation rates among older patients (17)], long-term, population-based QOL outcomes such as those presented in our study are a critical addition to the literature.

For patients who do choose a breast-conserving approach, the next decision they face is to select from a growing armamentarium of adjuvant local treatment options, including WBI (9, 27, 28), accelerated partial-breast irradiation (either external beam or brachytherapy) (11), and endocrine therapy without radiation therapy (7, 8). In our study we demonstrated that less or no irradiation is associated with better QOL outcomes overall, although this appears to be at the cost of a slightly higher risk of in-breast tumor recurrence. These findings are consistent with those of the CALGB (Cancer and Leukemia Group B) 9343 trial (7, 29), in which women who were randomized to no irradiation after lumpectomy reported less breast pain but had an increased risk of local recurrence. Notably, the rate of subsequent mastectomy was similarly low with both Lump + WBI and Lump alone. This finding is not surprising, given that patients treated with Lump alone are often eligible for a second course of breast-conserving therapy at the time of recurrence whereas breast-conserving therapy is more challenging in patients previously treated with brachytherapy.

Our finding of slightly higher in-breast recurrence and subsequent mastectomy rates among patients treated with Lump + Brachy versus Lump + WBI corroborates previously published data demonstrating an increased mastectomy rate in women treated with brachytherapy versus WBI in the United States (30–32). However, our data also suggest that this increased rate of in-breast recurrence and subsequent mastectomy does not, on average, translate into worse overall QOL scores for the population of patients receiving brachytherapy. In fact, cosmetic satisfaction, physical well-being, and adverse radiation effects were better with brachytherapy than with WBI. As new data emerge regarding the toxicity of brachytherapy compared with WBI (33, 34), our findings provide additional reassurance for providers concerned about long-term QOL outcomes in these patients.

Finally, for patients opting for mastectomy, many will face the decision of whether to undergo postmastectomy radiation therapy (PMRT), particularly given the mounting evidence for regional nodal irradiation in selected early-stage, node-positive patients (12, 13, 35). Indeed, claims data suggest that the use of PMRT in older women is increasing (36). Notably, none of the recently published randomized trials (12, 13) included formal evaluation of PROs. Our data suggest that the addition of adjuvant radiation therapy may have a meaningful adverse impact on a patient's long-term QOL, and these effects should be considered when deciding whether to deliver PMRT in older patients with borderline indications, although it is also possible that this observation was confounded by unmeasured differences in stage, intensity of chemotherapy, or other features between irradiated and unirradiated patients receiving mastectomy.

It is notable that despite the variations in QOL outcomes and recurrence rates across treatment strategies, there were no measurable differences in patient regret regarding patients' local therapy choices. In fact, patient regret was low overall, with adjusted scores ranging from 13.8 to 33.4 on a 100-point scale, with 100 representing the most regret. This finding suggests that most patients would make the same decisions if they had to do it all

over again, and it should provide some reassurance to patients with newly diagnosed breast cancer who are struggling to make decisions regarding their treatment.

Our study had several strengths. By using nationally comprehensive Medicare claims, we were able to study a population-based cohort treated across the country in a variety of clinical settings. In addition, all patients received diagnoses in 2009 and were surveyed at the end of 2015. This approach allowed us to compare patients treated in the same era with contemporary planning techniques and to compare patients for whom a similar amount of time had elapsed since treatment. Finally, our study was strengthened by its focus on older women. Local therapy issues are unique and merit focused study in older women because there are more guideline-concordant local therapy options than in younger women and because few older women receive postmastectomy breast reconstruction (16% in our study). Older women may also be at risk for greater side effects from surgery, radiation therapy, or systemic therapy, all of which may alter their long-term QOL compared with younger women (37).

Our study also had several limitations. First, our response rate was only 30%, despite following similar approaches to other studies of population-based samples of cancer patients (20, 38). This limitation highlights the challenges of engaging older breast cancer survivors many years after their diagnosis and limits power to measure small differences across treatment groups. Furthermore, there were some differences between responders and nonresponders; for example, women treated with lumpectomy alone were less likely to respond than women treated with other local therapies. In addition, responders tended to be younger than nonresponders (median age, 72 years for responders vs 75 years for nonresponders), and thus our findings should be interpreted with caution when extrapolating to populations that were underrepresented in our sample. However, as the focus of our study was on the comparison of outcomes across chosen local therapy, a strength is that our multivariable models could adjust for factors associated with response when such factors were associated with the outcome of interest.

A second limitation is the lack of information on tumor size and staging. Indeed, these are clinical features that factor into clinical decisions regarding local therapy, and it is certainly possible that patients treated with Lump + Brachy or Lump alone had smaller tumors than patients treated with Lump + WBI. However, to our knowledge, there are no studies demonstrating an association between tumor size and worse patient-reported cosmetic outcomes. In fact, in one randomized trial of standard versus hypofractionated WBI, T category was not a significant predictor of longitudinal patient-reported or physician-rated cosmesis (39). These findings suggest that tumor size may not be the most relevant predictor of patient-reported cosmetic satisfaction. Finally, we did not have information on baseline PROs. Such data may have mitigated the effect of confounders.

In summary, we found that less surgery and less irradiation were associated with better long-term QOL outcomes overall, with the caveat that patient-reported local recurrence rates were slightly higher among women who underwent a breast-conserving approach and did not receive WBI. Our study provides novel and much-needed PRO data across multiple local therapies that can be used to counsel patients who are faced with complex decisions

regarding local therapy. Equipped with data such as these, patients and their caregivers can partner to select a treatment to optimize long-term health-related QOL and satisfaction.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Summary

We surveyed older breast cancer survivors treated with 1 of 5 local therapy options (lumpectomy plus whole-breast irradiation [Lump + WBI], lumpectomy plus brachytherapy [Lump + Brachy], lumpectomy alone, mastectomy without radiation therapy, and mastectomy plus radiation therapy) to assess quality-of-life (QOL) outcomes 6 years after diagnosis. Compared with Lump + WBI, Lump + Brachy was generally associated with better QOL outcomes, while mastectomy plus radiation therapy was associated with worse QOL outcomes. Within the subgroup of patients treated with breast conservation, in-breast recurrence rates were slightly higher among patients treated with Lump + Brachy and lumpectomy alone compared with Lump + WBI.

Table 1

Patient characteristics by treatment group

	All patients (n = 489)*	Lump + WBI (n = 108)*	Lump + Brachy (n = 103)*	Lump alone (n = 78)*	Mast alone (n = 89)*	Mast + RT (n = 111)*	P value
Age at diagnosis							
Median (range), y	72 (67, 87)	73	72	73	72	72	
67–74 y, n (%)	335 (54.5)	75 (59.1)	72 (58.6)	53 (31.4)	63 (47.7)	72 (59.2)	
75 y, n (%)	154 (45.5)	33 (40.9)	31 (41.4)	25 (68.6)	26 (52.3)	39 (40.8)	.09
Patient-reported race, n (%)							
White	420 (86.4)	94 (86.7)	90 (87.3)	66 (86.3)	74 (85.7)	96 (86.7)	
Nonwhite	69 (13.6)	14 (13.3)	13 (12.7)	12 (13.7)	15 (14.3)	15 (13.3)	>.99
Charlson Comorbidity Index, n (%)							
0	329 (67.6)	76 (69.8)	73 (67.4)	48 (52.2)	63 (67)	69 (61.7)	
1	160 (32.4)	32 (30.2)	30 (32.6)	30 (47.8)	26 (33)	42 (38.3)	.75
Patient-reported baseline BMI, n (%)							
Underweight or normal weight	157 (38.1)	37 (38.9)	32 (33.0)	24 (48.3)	35 (39.3)	29 (28.0)	
Overweight	143 (24.9)	23 (22.1)	34 (33.3)	20 (22.4)	23 (22.9)	43 (46.0)	
Obese	157 (36.9)	40 (39)	34 (33.7)	29 (29.4)	27 (37.8)	27 (26.0)	.30
Unknown	32						
Patient-reported current bra cup size, n (%)							
A or B	152 (30.5)	32 (29.3)	32 (33.4)	25 (50.1)	29 (29.7)	34 (29.3)	
C	131 (26.8)	35 (32.8)	30 (27.4)	23 (21.6)	19 (19.2)	24 (20.8)	
D or larger	120 (24.4)	>20 (25.7)	>20 (29.5)	20 [†]	18 (23.1)	21 (18.2)	
Unknown	86 (18.3)	11 [†]	11 [†]	<11 [†]	23 (28.0)	32 (31.7)	.014
Axillary surgery, n (%)							
Axillary dissection or axillary surgery NOS	248 (47.6)	42 (38.7)	31 (27.8)	21 (21.7)	56 (60.7)	90 [†]	
Sentinel lymph node biopsy	164 (36.8)	47 (44)	52 (53.4)	27 (51.3)	23 [†]	11 (11.3)	
No axillary surgery	77 (15.6)	19 (17.3)	20 (18.8)	30 (27)	<11 [†]	<11 [†]	<.001
Patient-reported endocrine therapy, n (%)							
No	193 (46.8)	41 (41.4)	40 (38.0)	14 (14.9)	53 (62.1)	45 (41.0)	

	All patients (n = 489)*	Lump + WBI (n = 108)*	Lump + Brachy (n = 103)*	Lump alone (n = 78)*	Mast alone (n = 89)*	Mast + RT (n = 111)*	P value
Chemotherapy, n (%)							
Yes	296 (53.2)	67 (58.6)	63 (62.0)	64 (85.1)	36 (37.9)	66 (59.0)	<.001
No	348 (79.2)	90 (82.9)	92 [†]	68 [†]	68 (80.2)	26 (26.7)	
Yes	141 (20.8)	18 (17.1)	11 [†]	<11 [†]	21 (19.8)	85 (73.3)	<.001
Region, n (%)							
Northeast	83 (19.5)	24 (23.9)	16 (16.0)	10 (12.5)	12 [†]	>15 [†]	
Midwest	120 (25.2)	22 (19.2)	24 (21.2)	22 (43.0)	26 (34.0)	26 (24.2)	
South	212 (40.8)	41 (38.3)	48 (49.3)	30 (29.7)	41 (42.6)	52 (45.5)	
West	72 (14.4)	21 (18.6)	15 (13.5)	15 (14.2)	<11 [†]	<15 [†]	.03
Patient-reported education, n (%)							
High school or less	182 (42.8)	40 (39.6)	29 (29.1)	26 (28.6)	40 (51.7)	47 (45.5)	
Associate degree	157 (33.3)	38 (37.7)	34 (37.1)	25 (46.9)	25 (24.9)	35 (31.1)	
College or higher	131 (24)	23 (22.7)	35 (33.8)	24 (24.6)	23 (23.4)	26 (23.5)	.12
Unknown	19						
Patient-reported current household income, n (%)							
<\$40,000	213 (48.2)	49 (45.4)	30 (29.5)	41 (67.5)	43 (55.5)	50 (46.9)	
\$40,000–\$60,000	74 (12.1)	14 (11.9)	19 (17.6)	12 (9.7)	13 (10.8)	16 (14.0)	
>\$60,000	115 (22.3)	25 (22.6)	30 (29.6)	12 (9.7)	20 (20.9)	28 (24.4)	
Unknown	87 (17.4)	20 (20.1)	24 (23.3)	13 (13.0)	13 (12.7)	17 (14.8)	.19
Has smoked 100 cigarettes in lifetime, n (%)							
No	284 (59.8)	57 (57.3)	50 (54.1)	47 (66.5)	60 (62.8)	70 (66.4)	
Yes	185 (40.2)	44 (42.7)	47 (45.9)	28 (33.5)	29 (37.2)	37 (33.6)	.74
Unknown	20						

Abbreviations: BMI = body mass index; Lump alone = lumpectomy plus endocrine therapy alone; Lump + Brachy = lumpectomy plus brachytherapy; Lump + WBI = lumpectomy plus whole-breast irradiation; Mast alone = mastectomy alone; Mast + RT = mastectomy plus radiation therapy; NOS = not otherwise specified.

* All percentages are weighted percentages.

[†] Cells were suppressed to avoid compromising patient identity based on claims data in accordance with our Data Use Agreement with the Centers for Medicare & Medicaid Services.

Self-reported cancer outcomes relative to patients treated with lumpectomy and whole-breast irradiation

Table 2

	n	Any recurrence [*]		In-breast recurrence [*]		Subsequent mastectomy [*]		Recurrence elsewhere [*]		Contralateral breast cancer [*]		Second primary [*]	
		Referent		Referent		Referent		Referent		Referent		Referent	
Lump + WBI	108												
Lump + Brachy	103	5.2%		5.8%		5.9%		1.0%		-0.8%		4.0%	
Lump alone	78	6.3%		6.4%		-0.9%		2.0%		-1.1%		-1.7%	
Mast alone	89	8.1%		-		-		1.5%		4.2%		-2.0%	
Mast + RT	111	1.6%		-		-		0.8%		-1.9%		-3.3%	
P value [†]		.30		.01		<.001		.94		.27		.76	

Abbreviations: Lump alone = lumpectomy plus endocrine therapy alone; Lump + Brachy = lumpectomy plus brachytherapy; Lump + WBI = lumpectomy plus whole-breast irradiation; Mast alone = mastectomy alone; Mast + RT = mastectomy plus radiation therapy.

^{*} The actual risks of events cannot be reported because of Centers for Medicare & Medicaid Services regulations. As a result, risks are reported relative to the risk among patients treated with Lump + WBI. For example, the risk of patient-reported in-breast recurrence was 5.8% higher among patients treated with Lump + Brachy compared with Lump + WBI.

[†] Fisher exact test.

CanSORT Satisfaction with Breast Cosmetic Outcome and BREAST-Q Satisfaction with Breast scores

Table 3

	CanSORT* (n = 477) [†]			BREAST-Q ^{‡,§} (n = 451) [¶]		
	n	Mean (95% CI)	P value	n	Mean (95% CI)	P value
Lump + WBI	107	3.40 (3.14–3.67)	Referent	104	60.00 (53.04–66.95)	Referent
Lump + Brachy	101	3.77 (3.54–4.00)	.007	98	66.95 (59.85–74.04)	.03
Lump alone	74	3.80 (3.50–4.09)	.045	71	67.82 (57.48–78.17)	.12
Mast alone	87	3.11 (2.83–3.40)	.06	82	59.27 (51.83–66.72)	.83
Mast + RT	108	3.01 (2.77–3.25)	.006	96	50.24 (43.62–56.85)	.001

Abbreviations: CanSORT = Cancer Surveillance and Outcomes Research Team; CI = confidence interval; Lump alone = lumpectomy plus endocrine therapy alone; Lump + Brachy = lumpectomy plus brachytherapy; Lump + WBI = lumpectomy plus whole-breast irradiation; Mast alone = mastectomy alone; Mast + RT = mastectomy plus radiation therapy.

*The final model for the CanSORT instrument was adjusted for Charlson Comorbidity Index.

[†]Patients were included if they had 1 nonmissing response to the CanSORT instrument.

[‡]The final model for BREAST-Q Satisfaction with Breast was adjusted for race, Charlson Comorbidity Index, and patient-reported endocrine therapy.

[§]CanSORT and BREAST-Q satisfaction scores were highly correlated with each other (Spearman coefficient = 0.8, $P < .001$).

[¶]Patients were included if they had 50% nonmissing responses; missing responses were assigned a value based on the mean of the nonmissing responses (in accordance with BREAST-Q scoring tables).

Table 4

Adjusted BREAST-Q patient-reported outcomes by treatment group

	Psychosocial well-being [*] (n = 455) [†]				Sexual well-being [‡] (n = 198) [†]				Physical well-being [§] (n = 453) [†]				Adverse radiation effects (n = 201) [†]			
	n	Mean	(95% CI)	P value	n	Mean	(95% CI)	P value	n	Mean	(95% CI)	P value	n	Mean	(95% CI)	P value
Lump + WBI	103	75.9	(69.8–82.0)	Referent	41	49.1	(41.4–56.7)	Referent	104	81.4	(78.2–84.6)	Referent	103	90.4	(86.7–94.1)	Referent
Lump + Brachy	99	78.3	(72.7–83.9)	.40	41	55.1	(43.7–66.5)	.30	97	86.9	(83.4–90.5)	.02	98	94.8	(90.2–99.5)	.04
Lump alone	74	75.8	(69.8–81.8)	.97	30	53.2	(42.3–64.1)	.49	74	79.7	(74.8–84.5)	.55	–	–	–	–
Mast alone	81	69.9	(63.6–76.2)	.06	36	40.4	(29.4–51.4)	.17	82	81.6	(77.5–85.6)	.94	–	–	–	–
Mast + RT	98	64.3	(57.7–71.0)	<.001	50	27.2	(16.4–38.0)	<.001	96	73.0	(69.2–76.7)	<.001	–	–	–	–

Abbreviations: CI = confidence interval; Lump alone = lumpectomy plus endocrine therapy alone; Lump + Brachy = lumpectomy plus brachytherapy; Lump + WBI = lumpectomy plus whole-breast irradiation; Mast alone = mastectomy alone; Mast + RT = mastectomy plus radiation therapy.

^{*}The model for BREAST-Q psychosocial well-being was adjusted for Charlson Comorbidity Index and axillary surgery.

[†]For each section, patients were included if they had 50% nonmissing responses in that section; missing responses were assigned a value based on the mean of the nonmissing responses (in accordance with BREAST-Q scoring tables).

[‡]The model for BREAST-Q sexual well-being was adjusted for Charlson Comorbidity Index, axillary surgery, and geographic region.

[§]The model for BREAST-Q physical well-being was adjusted for age, bra cup size, and geographic region.

^{||}The model for BREAST-Q adverse radiation effects was adjusted for race and bra cup size.

Table 5

Decisional regret and EQ-5D-3L health utilities by treatment group

	Surgery regret [*] (n = 463)			Radiation therapy regret ^{†,‡} (n = 340)			EQ-5D-3L [§] (n = 466)		
	n	Mean (95% CI)	P value	n	Mean (95% CI)	P value	n	Mean (95% CI)	P value
Lump + WBI	105	19.4 (9.8–29.0)	Referent	103	28.5 (18.3–38.8)	Referent	106	0.86 (0.81–0.90)	Referent
Lump + Brachy	101	17.7 (8.5–26.8)	.52	99	27.2 (17.0–37.4)	.63	100	0.88 (0.84–0.92)	.23
Lump alone	74	13.8 (3.4–24.2)	.09	34	24.6 (14.1–35.0)	.28	72	0.85 (0.79–0.90)	.73
Mast alone	83	20.1 (10.8–29.4)	.81	–	–	–	86	0.79 (0.73–0.86)	.15
Mast + RT	100	22.0 (12.9–31.2)	.28	104	33.4 (23.6–43.2)	.10	102	0.78 (0.73–0.82)	.004

Abbreviations: CI = confidence interval; Lump alone = lumpectomy plus endocrine therapy alone; Lump + Brachy = lumpectomy plus brachytherapy; Lump + WBI = lumpectomy plus whole-breast irradiation; Mast alone = mastectomy alone; Mast + RT = mastectomy plus radiation therapy.

^{*}The model for surgery regret was adjusted for race, Charlson Comorbidity Index, patient-reported education, and income.

[†]The model for radiation therapy regret was adjusted for race, Charlson Comorbidity Index, baseline body mass index, and region.

[‡]For the Lump alone group, the outcome was decisional regret regarding skipping radiation therapy.

[§]The model for EQ-5D-3L was adjusted for Charlson Comorbidity Index, chemotherapy, and patient-reported income.