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Disparities in the Use of Postmastectomy Radiation Therapy for Inflammatory Breast Cancer

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Abstract

Purpose—Although radiation therapy improves locoregional control and survival for inflammatory breast cancer (IBC), it is underused in this population. The purpose of this study was to identify variables associated with the underuse of postmastectomy radiation therapy (PMRT) for IBC.

Methods and Materials—Using the 1998 to 2011 National Cancer Data Base, we identified 8273 women who underwent mastectomy for nonmetastatic IBC. We used logistic regression modeling to determine the demographic, tumor, and treatment variables associated with the underuse of PMRT.

Results—Although the use of PMRT increased over time, a total of 30.3% of our cohort did not receive PMRT. On multivariate analysis, variables associated with the underuse of PMRT for IBC included the following (all $P < .05$): Medicare insurance (odds ratio [OR] = 0.70), annual income < \$34,999 (<\$30,000: OR=0.79; \$30,000–\$34,999: OR=0.82), cN2 and cN0 disease (cN2: OR=0.71; cN0: OR=0.63), failure to receive chemotherapy and hormone therapy (chemotherapy: OR=0.15; hormone therapy: OR=0.35), treatment at lower-volume centers (OR=0.83), and treatment in the South and West (South: OR=0.73; West: OR=0.80). Greater distance between patient's residence and radiation facility was also associated with the underuse of PMRT ($P = .0001$).

Conclusions—Although the use of PMRT for IBC has increased over time, it continues to be underused. Disparities related to a variety of variables impact which IBC patients receive PMRT. A concerted effort must be made to address these disparities in order to optimize the outcomes for IBC. Published by Elsevier Inc.

Introduction

In addition to systemic therapy and surgery, radiation therapy is recommended by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines as a standard component of trimodality therapy for non-metastatic inflammatory breast cancer (IBC) (1). In general, IBC patients are recommended to undergo neoadjuvant chemotherapy followed by modified radical mastectomy and postmastectomy radiation therapy (PMRT). Treatment concludes with long-term hormone therapy in hormone receptor-positive patients (1).

Radiation therapy has been shown to improve locoregional control and overall survival in IBC (2, 3). In a National Cancer Data Base (NCDB) study published last year, our group demonstrated that the addition of radiation therapy to systemic therapy and surgery was associated with an improved 10-year overall survival from 29% to 37%. However, radiation therapy was found to be under-used in this population. In fact, a total of 27% of patients who received systemic therapy and surgery did not receive radiation therapy (3). Such underuse of PMRT has also been found in non-IBC populations (4).

The purpose of this follow-up study was to identify the variables associated with the underuse of PMRT in IBC, highlighting any disparities related to demographic, tumor, and treatment variables. We thereby aim to identify key target populations for future interventions designed to increase the use of PMRT.

Methods and Materials

Data source

The data source for our study was the NCDB, a clinical oncology database sponsored by the American College of Surgeons and the American Cancer Society. The NCDB contains deidentified demographic, tumor, treatment, and outcome information on nearly 30 million patients from facilities accredited by the Commission on Cancer in the United States and Puerto Rico (5).

Our study was deemed exempt from review by the local Institutional Review Board Human Subjects Committee under Federal Regulations Code 45 part 46.101(b).

Study cohort and variables

Female patients with IBC of any histologic subtype and any nodal status who underwent mastectomy between 1998 and 2011 were eligible for inclusion. This study period was chosen because it included the broadest time frame and the most recent data available from the NCDB at the time of the analysis. Patients with prior cancer, metastatic disease, radiation therapy before mastectomy, non-external beam radiation therapy, missing radiation therapy data, and those diagnosed by autopsy or death certificate were excluded.

Demographic, tumor, and treatment information was collected. Demographic variables included age at diagnosis, race, Charlson-Deyo Comorbidity Score (CDCS), insurance status, education, income, community population density, and year of diagnosis. Tumor

variables included grade and clinical nodal stage according to the American Joint Committee on Cancer Tumor Node Metastasis staging system in use at the time of diagnosis. Treatment variables included operation performed, margin status, use of PMRT, chemotherapy, hormone therapy, facility type and location, and travel distance between patient's residence and radiation facility. The NCDB includes a variable entitled "reason for no radiation," which enabled capture of reasons why PMRT was not delivered.

For facility type, higher-volume centers were defined as those that treat over 500 new cancers each year, provide a full range of diagnostic and treatment services, and also participate in clinical research. In regard to facility location, the NCDB regions of New England and Middle Atlantic were classified as Northeast; South Atlantic, East South Central, and West South Central were classified as South; East North Central and West North Central were classified as Midwest; and Mountain and Pacific were classified as West.

The variables of hormone and Her2 receptor status, lymphovascular invasion, chemotherapy–surgery sequence, and response to neoadjuvant chemotherapy were excluded from the analysis because of a prohibitive amount of missing data.

Statistical analysis

Univariate analyses were performed to evaluate the association between each variable and the underuse of PMRT; χ^2 tests were used for categorical variables; and t tests and analyses of variance, or their nonparametric counterparts, were used for continuous variables. Logistic regression analysis was then used to assess the multivariate relationship between the variables and the underuse of PMRT. Specifically, a logistic regression model was obtained by first including an initial set of candidate variables with $P < .05$ in the univariate analysis. A backward stepwise elimination was then performed using $P < .05$ as the significance level for a variable to remain in the model (6).

The CDCS was not collected by the NCDB until 2003. The model building procedures were consequently performed twice to assess the impact of inclusion versus exclusion of CDCS on the multivariate results. First, CDCS was included in the modeling, which limited the analysis to patients treated between 2004 and 2011. Then, CDCS was excluded, which enabled capture of all patients treated between 1998 and 2011. CDCS was not a significant variable in the first multivariate model. It was therefore excluded from the multivariate analysis reported in our study to maximize sample size and follow-up time. However, recognizing the importance of controlling for co-morbidity in this population, we individually assessed the variables found to be significant in the multivariate model of PMRT use for potential confounding by CDCS using Cochran-Mantel-Haenszel statistics.

To assess the impact of travel distance between a patient's residence and radiation facility on the use of PMRT, a separate analysis was performed excluding patients who received PMRT at a facility other than the reporting facility. NCDB distance data refers to that between the patient's residence and the reporting facility. This exclusion was not applied to the general cohort used for the other analyses.

For all analyses, SAS version 9.2 (SAS Institute, Cary, NC) and S-Plus version 8.04 (Statistical Sciences, Seattle, WA) were used to carry out the computations. A 2-sided P value $<.05$ was used in all tests of significance.

Results

A total of 8273 patients met the eligibility criteria and were included in the study. Table 1 describes the characteristics of the cohort. The median age at diagnosis was 55 years (range, 21–90 years). Most patients were white, had no comorbidities, were of higher socioeconomic status, and were from metropolitan areas. A majority of the tumors were poorly differentiated and clinically node positive. Although more than 80% of patients underwent a radical or modified radical mastectomy, 13.6% underwent a total mastectomy without an examination of the lymph nodes. Negative microscopic and macroscopic margins were achieved in 82.3%. Only 6.6% underwent reconstruction, the majority being tissue based without implants.

Postmastectomy radiation therapy was not delivered in 30.3%, the most common reason being that the patient chose a treatment plan that did not include PMRT after being offered multiple therapeutic options (86.4%). Other reasons for PMRT not being delivered were that it was refused by the patient (7.3%), recommended but with the reason for nondelivery unknown (3.7%), and contra-indicated because of patient disease (2.7%). Chemotherapy was administered in a majority of patients, whereas less than half received hormone therapy. Most patients were treated in higher-volume centers and in the South.

Figure 1 depicts the use of PMRT over time. Although the use of PMRT increased from 58.5% in 1998 to a maximum of 78.0% in 2007, a total of 27.0% of patients did not receive PMRT in 2011, the most recent year studied.

On univariate analysis, the following demographic, tumor, and treatment variables were significantly associated with the underuse of PMRT: age at diagnosis, race, insurance status, education, income, clinical nodal stage, operation performed, margin status, chemotherapy, hormone therapy, facility type, and facility location.

Table 2 presents the results of the multivariate analysis. The following significant univariate variables were not found to be significant on multivariate analysis: age at diagnosis, race, education, operation performed, and margin status. None of the significant variables in the multivariate model were found to be confounded by CDCS.

Insurance status and income were significant demographic predictors of the underuse of PMRT. Compared with patients with private insurance, patients with Medicare were less likely to receive PMRT (odds ratio [OR] =0.70). There was also a trend toward patients with Medicaid and the uninsured being less likely to receive PMRT (OR=0.86 and 0.79, respectively). Furthermore, patients with annual incomes less than \$35,000 were less likely to receive PMRT than were those with annual incomes greater than or equal to \$46,000 (OR=0.79 for $<\$30,000$; 0.82 for $\$30,000$ – $\$34,999$).

Clinical nodal stage was the only tumor-related variable that predicted the underuse of PMRT. Compared with patients with N3 disease, patients with N2 and N0 disease were less likely to receive PMRT (OR=0.71 and 0.63, respectively).

In regard to treatment variables, patients who did not receive chemotherapy, hormone therapy, or both were far less likely to receive PMRT than were those who received these therapies (OR=0.15 and 0.35, respectively). In addition, patients in lower-volume centers were less likely to receive PMRT than were those in higher-volume centers (OR=0.83). Finally, patients treated in the South and West were less likely to receive PMRT than were those treated in the Midwest and Northeast (OR=0.73 and 0.80, respectively).

Figure 2 illustrates the impact of travel distance between patient's residence and radiation facility on the use of PMRT. A total of 17.7% of patients received PMRT at a facility other than the reporting facility and were excluded from this analysis. Among the remaining patients, the median travel distance was 8.6 miles. There was a significant inverse relationship between travel distance and the use of PMRT, with a 7% difference in the rates of PMRT between those who lived within 4.1 miles of the radiation facility versus those who lived over 18.8 miles away (66.3% vs 59.3%, $P=.0001$).

The reduced use of PMRT in the South and West revealed in the multivariate analysis was not completely explained by greater travel distances. Whereas the South had the longest median travel distance of 9.9 miles, the West had the second shortest median travel distance of 8.1 miles. The median travel distances in the Northeast and Midwest were 6.9 and 8.9 miles, respectively.

Discussion

The IBC cohort analyzed in our study is similar to IBC populations described in the literature. On average, the patients were relatively young at diagnosis and presented with poorly differentiated, node-positive tumors. According to Surveillance, Epidemiology, and End Results (SEER) data, the median age at diagnosis for IBC versus non-IBC patients is 57 and 62 years, respectively (7). In addition, IBC tumors are 2 to 3 times more likely to be poorly differentiated and 4 to 5 times more likely to be node positive (7, 8). The SEER data also suggest that IBC disproportionately affects black women, with a relative incidence of 3.1 per 100,000 woman-years in comparison with 2.2 per 100,000 woman-years for white women (8). We did not find this to be the case in our cohort. Rather, the race composition of IBC patients in the NCDB is reflective of the US population as a whole (9).

Despite the increasing use of PMRT over time, rates have remained stagnant in the 70% to 80% range since 2003. Furthermore, PMRT was not delivered to over 30% of this cohort. This figure is consistent with our prior finding of radiation therapy not being delivered to 27% of IBC patients who underwent both surgery and chemotherapy (3). The rates of nonreceipt of PMRT reported in the literature for noninflammatory but locoregionally advanced breast cancer are even higher, ranging from approximately 35% to 50% (10, 11). Although it is possible that some patients in this cohort did not receive PMRT because they had progressive disease or were in transition toward palliative care, we sought to minimize

this percentage by including only those patients who were sufficiently fit to undergo surgery and were therefore more likely to be candidates for complete trimodality therapy. In fact, patient refusal and contraindication due to patient disease accounted for only 10% of the group that did not receive PMRT.

Our analysis suggests that patients with Medicare insurance and lower income were significantly less likely to receive PMRT. In addition, there was a trend toward patients with Medicaid and the uninsured also being less likely to receive PMRT. These findings corroborate those of several other studies in which socioeconomic status impacts breast cancer treatment (12–16). Surprisingly, neither age nor race was a significant predictor of the underuse of PMRT in the multivariate analysis. In the breast conservation therapy population, several studies have found advanced age and nonwhite race to be associated with the underuse of radiation therapy (17, 18).

Patients not treated with chemotherapy and hormone therapy were significantly less likely to receive PMRT than those treated with these therapies. This finding likely reflects a less aggressive approach in the treatment of a subgroup of IBC patients, such as those with progressive disease and those choosing palliation. Similar findings have been replicated in other patient populations. For instance, in a 2011 study using SEER-Medicare data, patients with locoregionally advanced breast cancer not treated with chemotherapy were 33% less likely to receive PMRT than were those treated with chemotherapy (11). Moreover, in a recently published NCDB study also evaluating PMRT use in locoregionally advanced breast cancer, patients treated with chemotherapy were 4.55 times more likely to receive PMRT than were those who were not (10).

Facility type was a significant predictor of the underuse of PMRT for IBC, with lower-volume centers being 17% less likely to deliver PMRT than were higher-volume centers. This difference may be due to patient referral patterns, more experience in the treatment of IBC, a greater availability of radiation facilities in higher-volume centers, or a combination of these factors. Although the definition of a higher-volume center varies in the literature, several studies support a relationship between higher-volume centers and improved breast cancer outcomes. In one report from Taiwan, the risk of death resulting from breast cancer in lower-volume centers was 1.48 times greater than in higher-volume centers (19). In another study using Los Angeles County Cancer Surveillance data, there was a 23% reduction in the risk of death from breast cancer at 5 years among patients treated in higher-volume centers (20).

Facility location was also associated with the underuse of PMRT, with IBC patients in the South and West being less likely to receive PMRT than those in the Midwest and Northeast. This finding is corroborated by another NCDB study of locoregionally advanced breast cancer that found the highest rates of PMRT in the Northeast and the lowest rates in the West (21). Inasmuch as travel distance did not completely explain these geographic differences in PMRT use, the exact reasons underlying these disparities remain to be clarified.

Nonetheless, travel distance was independently found to be significantly associated with the use of PMRT. PMRT generally involves 1 to 2 daily treatments for several weeks. A long

travel distance to a radiation facility can be burdensome, and sometimes prohibitive, for patients. The relationship between travel distance and receipt of radiation therapy is supported in the literature (22–25). In one study, breast conservation therapy patients living more than 20 miles from the radiation facility were nearly 30% less likely to receive treatment (24). In another study of elderly women undergoing mastectomy, a decline in PMRT use was apparent with travel distances over 25 miles (22).

In addition to disparities in the use of PMRT related to socioeconomic status, facility type, facility location, and travel distance, our study also revealed a lack of consensus and incomplete adoption of national guidelines among health care providers treating IBC. For instance, more than 10% of patients underwent a total mastectomy without an examination of the lymph nodes, even though NCCN guidelines recommend a level I and II axillary lymph node dissection. Interestingly, an inadequate surgical procedure such as a total mastectomy without an examination of the lymph nodes did not predict use of PMRT. Furthermore, the most common reason for failure to administer PMRT was that the patient chose a treatment plan that did not include PMRT after being offered multiple therapeutic options. In the absence of contraindications to PMRT, treatment plans for IBC should consistently include PMRT in accordance with NCCN guidelines recommending PMRT as a standard component of trimodality therapy. The delivery of PMRT must also be of high quality, with 3-dimensional planning and attention to Radiation Therapy Oncology Group guidelines (26, 27). Finally, clinical nodal stage was found to be a significant predictor of the underuse of PMRT on multivariate analysis. Patients with less nodal involvement were less likely to receive PMRT, notwithstanding the NCCN guidelines, which recommend PMRT for patients with any degree of nodal involvement, including node-negative patients. Finally, although some studies have questioned the role of PMRT in low-risk patients with a complete pathologic response after neoadjuvant chemotherapy, no studies have supported this approach in IBC, to our knowledge (28, 29). Given that a significant percentage of patients had no comorbidities, were of higher socioeconomic status, and were from metropolitan areas, neither medical contraindications nor socioeconomic or geographic barriers fully explain the underuse of PMRT in this population. Decision making by health care providers appears to be a contributing factor.

The use of a large national database subjects these data to misclassification error and reporting bias. Furthermore, a recent report published in this journal demonstrated that population-based tumor registries are particularly variable in the accuracy of radiation therapy coding when compared with Medicare claims (30). There is also the potential for confounding by uncaptured variables, such as resectability, progression of disease, and response to neoadjuvant chemotherapy, which may have influenced the use of PMRT. Furthermore, the interpretation of the hormone therapy variable is limited by the absence of data on hormone receptor positivity. Nonetheless, these weaknesses are balanced by the ability to analyze a cohort with a large sample size.

In conclusion, disparities exist in the use of PMRT for IBC patients. The disparities identified in our study relate to a variety of demographic, tumor, and treatment variables. Socioeconomic and geographic barriers to care are evident. Clearly, more resources are needed to support patients during treatment. These resources could be directed toward child

care, transportation, and employers' support of medical leave. There is also a need for greater consensus and adoption of national guidelines among health care providers. Continuing medical education is critical to ensure that physicians remain abreast of changes in the standard of care. Last, systems of care at higher-volume centers, which often include specialists and multidisciplinary teams, should be applied to lower-volume centers. Collaborations between higher-volume and lower-volume centers that allow for sharing of information and resources will be key. In light of data supporting the positive impact of PMRT on locoregional control and overall survival in IBC, it is vitally important we address these disparities to optimize the outcomes for our patients.

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Summary

Using the National Cancer Data Base, we identified the demographic, tumor, and treatment variables associated with the underuse of postmastectomy radiation therapy for inflammatory breast cancer (IBC). Insurance status, income, nodal stage, use of systemic therapy, facility volume, and geographic variables were found to impact the use of this modality for IBC patients.

Fig. 1.
Postmastectomy radiation therapy (PMRT) use over time ($P<.0001$).

Fig. 2. Postmastectomy radiation therapy (PMRT) use versus travel distance between a patient's residence and radiation facility ($P<.0001$).

Table 1

Cohort characteristics (N=8273 patients)

Characteristic	n	%*
Demographic		
Age at diagnosis (y)		
<40	750	9.1
40–49	1897	22.9
50–59	2520	30.5
60–69	1713	20.7
70	1393	16.8
Race		
White	6726	81.3
Black	1195	14.4
Other	255	3.1
Unknown	97	1.2
CDCS		
0	4299	52.0
1	722	8.7
2	154	1.9
Unknown	3098	37.5
Insurance status [†]		
Private	4551	55.0
Medicare	2115	25.6
Medicaid	942	11.4
Other government	67	0.8
Uninsured	384	4.6
Unknown	214	2.6
Education [‡]		
<14%	2631	31.8
14%–19.9%	1831	22.1
20%–28.9%	1895	22.9
29%	1516	18.3
Unknown	400	4.8
Income (\$)§		
46,000	3020	36.5
35,000–45,999	2185	26.4
30,000–34,999	1479	17.9
<30,000	1190	14.4
Unknown	399	4.8
Population density		
Metro	6518	78.8

Characteristic	n	%*
Urban	1195	14.4
Rural	135	1.6
Unknown	425	5.1
Tumor		
Grade		
Well differentiated	171	2.1
Moderately differentiated	1804	21.8
Poorly differentiated	4870	58.9
Undifferentiated	185	2.2
Unknown	1243	15.0
Clinical nodal stage		
3	588	7.1
2	1309	15.8
1	3322	40.2
0	1922	23.2
Unknown	1132	13.7
Treatment		
Operation		
Total mastectomy	1125	13.6
Modified radical mastectomy	6915	83.6
Radical mastectomy	169	2.0
Unknown	64	0.8
Margin status//		
Negative	6806	82.3
Positive	975	11.8
Unknown	492	6.0
PMRT		
Delivered	5769	69.7
Not delivered	2504	30.3
Chemotherapy		
Administered	7826	94.6
Not administered	425	5.1
Unknown	22	0.3
Endocrine therapy		
Administered	2901	35.1
Not administered	5141	62.1
Unknown	231	2.8
Facility type		
Higher-volume centers	7119	86.1
Lower-volume centers	935	11.3
Other	219	2.7
Facility location		

Characteristic	n	% [*]
Midwest	2175	26.3
Northeast	1619	19.6
South	2943	35.6
West	1536	18.6

Abbreviations: CDCS = Charlson-Deyo Comorbidity Score; PMRT = postmastectomy radiation therapy.

^{*} Some group percentages may not sum exactly to 100% because of rounding at the thousandths level.

[†] Medicare is a federal-funded program that provides health insurance to the elderly and those with disabilities. Medicaid is a federal-funded and state-funded program that provides health insurance to those with low income.

[‡] Education data refers to percentage of adults in patient's zip code who did not graduate from high school.

[§] Income data refers to median household income in patient's zip code.

// Negative margin status indicates no residual microscopic/macrosopic tumor. Positive margin status indicates presence of residual microscopic/macrosopic tumor.

Table 2

Patient demographic, tumor, and treatment variables associated with underuse of PMRT on multivariate analysis

Variable	Odds ratio	95% confidence interval
Demographic		
Insurance status *		
Private	1.00	
Medicare	0.70	0.61–0.80
Medicaid	0.86	0.71–1.03
Other Government	1.33	0.69–2.58
Uninsured	0.79	0.61–1.03
Unknown	0.78	0.55–1.12
Income (\$) *		
46,000	1.00	
35,000–45,999	1.03	0.89–1.19
30,000–34,999	0.82	0.70–0.96
<30,000	0.79	0.67–0.94
Tumor		
Clinical nodal stage *		
3	1.00	
2	0.71	0.55–0.92
1	0.84	0.66–1.06
0	0.63	0.49–0.80
Treatment		
Chemotherapy *		
Administered	1.00	
Not administered	0.15	0.12–0.20
Endocrine therapy *		
Administered	1.00	
Not administered	0.35	0.30–0.40
Facility type *		
Higher-volume centers	1.00	
Lower-volume centers	0.83	0.69–0.99
Other	0.76	0.53–1.08
Facility location *		
Midwest	1.00	
Northeast	1.00	0.84–1.20
South	0.73	0.63–0.85
West	0.80	0.67–0.95

Abbreviation: PMRT = postmastectomy radiation therapy.

* All $P < .05$.