

Adoption of Intensity-Modulated Radiation Therapy for Breast Cancer in the United States

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Background Although intensity modulation of the radiation beam has been shown to lower toxic effects for patients receiving whole-breast irradiation, relatively simple techniques may suffice. It is thus controversial whether such treatment justifies billing for intensity-modulated radiation therapy (IMRT).

Methods We used the claims data to determine billing for IMRT from Surveillance, Epidemiology, and End Results–Medicare records from 2001 to 2005 for 26 163 women aged 66 years or older with nonmetastatic breast cancer treated with surgery and radiotherapy. The impact of individual covariates (demographic, health services, tumor, and treatment factors) on cost of treatment was assessed using the Wilcoxon two-sample test. Two-sided multivariable logistic regression was used to identify predictors for IMRT use. Cost of radiation was calculated in 2005 dollars. All statistical tests were two-sided.

Results The number of patients with IMRT billing claims increased from 0.9% (49 of 5196) of patients diagnosed in 2001 to 11.2% (564 of 5020) in 2005. In multivariable analysis, IMRT billing was more likely for patients with left-sided tumors (odds ratio [OR] = 1.30, 95% confidence interval [CI] = 1.16 to 1.45), for those residing in a health service area with high radiation oncologist density (OR = 2.32, 95% CI = 1.47 to 3.68), for those treated at freestanding radiation centers (OR = 1.36, 95% CI = 1.20 to 1.53), or for those residing in regions where the Medicare intermediary allowed breast IMRT (OR = 10.87, 95% CI = 9.26 to 12.76, all $P < .001$). The mean cost of radiation was \$7179 without IMRT and \$15 230 with IMRT. IMRT adoption contributed to an increase in the mean cost of breast radiation from \$6334 in 2001 to \$8473 in 2005.

Conclusions IMRT billing increased 10-fold from 2001 through 2005, contributing to a 33% increase in the cost of breast radiation. These findings suggest that reimbursement policy and practice setting strongly influenced adoption of IMRT billing for breast cancer.

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Breast cancer is the most common cancer treated with radiation therapy in the United States, with approximately 120 000 women treated annually (1). For women with breast cancer, multiple high-quality randomized trials have demonstrated that radiation therapy plays an important role in enabling breast conservation, optimizing local-regional control, and improving survival (2). Although generally well tolerated, radiotherapy to the breast or chest wall may be associated with acute toxic effects such as dermatitis and late toxic effects such as soft tissue fibrosis and cardiovascular sequelae (3–5). The historic limitations of conventional radiotherapy delivered with two-dimensional planning may have contributed to the severity of these toxic effects. Specific limitations of two-dimensional radiotherapy include the inability to accurately calculate volumetric dose distributions and to account for dose inhomogeneity in off-axis planes and reliance on static wedge compensators of fixed dimensions, which often do not optimally account for irregular tissue separations.

To reduce the risk of radiation toxicity, three-dimensional treatment planning and dynamic multileaf collimators have been used to modulate the radiotherapy dose in three dimensions across the breast and chest wall, thereby improving the homogeneity of the dose deposited. A growing body of evidence now suggests that such three-dimensional modulation of the radiation beam profile improves dose homogeneity within the treated breast (6) and lowers dose to the contralateral breast (7) and, potentially, the heart (8,9). In addition, recently published randomized trials have demonstrated that this dosimetric gain translates into a lower risk of acute skin toxicity (10) and improved long-term cosmetic outcome for patients receiving whole-breast irradiation following conservative surgery (11,12).

These clinically beneficial techniques that involve three-dimensional modulation of the radiation beam profile can be achieved using intensity-modulated radiation therapy (IMRT) or with other techniques that do not require IMRT (10,13–19). Prior research

has indicated that treatment with IMRT is associated with increased cost (20), but to date, it is not known to what extent IMRT is used in the treatment of breast cancer and what factors may have affected its adoption. Identifying factors that promote the use of a more costly therapy is critically important, given the imperative to promote cost-effective value-oriented practice in today's health-care environment (21). Accordingly, we used population-based data to characterize adoption of IMRT billing for patients diagnosed with breast cancer between 2001 and 2005, to identify demographic, health services, tumor, and treatment factors associated with the use of IMRT billing, and to compare the cost of care between radiation therapy with and without IMRT billing.

Materials and Methods

Data Source and Study Sample

We used Surveillance, Epidemiology, and End Results (SEER)–Medicare data, which capture clinical, pathological, and insurance claims data for Medicare beneficiaries diagnosed with a new cancer, who reside within one of 16 geographic catchment areas representing approximately 26% of the US population (22). We identified 65 820 women aged 66 years and older diagnosed with an incident breast cancer between 2001 and 2005 for whom complete Medicare billing claims were available (continuous part A and B coverage and no health maintenance organization coverage from 12 months before diagnosis through 12 months after diagnosis) (Table 1). We excluded patients who fit any of the following criteria: dead within 12 months of diagnosis, second cancer diagnosed within 12 months of breast cancer, history of cancer, nonepithelial histology (23), pure lobular carcinoma in situ, distant metastasis at diagnosis, unknown SEER historic stage at diagnosis (22), no pathological confirmation, and no definitive surgery, yielding 53 438 remaining patients. Of these, we selected only patients for whom common procedural terminology (CPT)–4 codes (Table 2) documented delivery of at least one and no more than 40 fractions of radiation therapy. We also excluded patients who received brachytherapy, yielding 26 163 patients for the final analytic sample (Tables 1 and 2).

CONTEXTS AND CAVEATS

Prior knowledge

Intensity-modulated radiation therapy (IMRT) for breast cancer has been used to reduce the risk of radiation toxicity, although similar clinical benefits can be achieved with techniques that do not require IMRT. Nevertheless, charges for IMRT are higher than for more standard techniques. The clinical, demographic, and economic factors associated with adoption of IMRT are not well defined.

Study design

Adoption of IMRT billing for patients with primary nonmetastatic breast cancer treated with radiation therapy between 2001 and 2005 was assessed from Surveillance, Epidemiology, and End Results–Medicare data. Demographic, health services, tumor, and treatment factors associated with the use of IMRT billing were used to compare the cost of care between radiation therapy with and without IMRT.

Contribution

Billing for IMRT treatment increased more than 10-fold from 2001 through 2005, contributing to a 33% increase in the cost of breast radiation. IMRT treatment was more frequently used in regions with Medicare Carrier coverage favorable toward breast IMRT and in freestanding radiation centers as compared with hospital-based outpatient clinics.

Implications

Reimbursement policy and practice setting can strongly influence the adoption of IMRT billing for breast cancer, even though less costly techniques may provide similar clinical benefits.

Limitations

The cohort was limited to older women who were Medicare beneficiaries. IMRT was defined exclusively from claims data and not validated by chart review. The cost analysis was conducted from a payer's perspective and did not consider patient co-payments or coinsurance and may not accurately reflect the cost to patients with private insurance.

From the Editors

Table 1. Study participants and exclusion criteria*

Step	Criteria	No. of remaining case patients
1	Women aged ≥ 66 y with incident breast cancer diagnosed during 2001–2005 with complete Medicare claims from 12 mo before to 12 mo following diagnosis	65 820
2	Exclude if died within 12 mo of diagnosis	65 243
3	Exclude if second cancer diagnosed within 12 mo of incident breast cancer	62 209
4	Exclude if history of cancer	58 368
5	Exclude if histology not consistent with epithelial breast cancer	57 169
7	Exclude if only breast cancer is lobular carcinoma in situ	56 625
8	Exclude if distant metastasis found at time of presentation	54 868
9	Exclude if stage not reported	54 264
10	Exclude if no pathological confirmation	>54 253
11	Exclude patients with biopsy only (no mastectomy or breast-conserving surgery documented)	53 438
12	Exclude patients who did not have documentation of radiation using common procedural terminology codes	27 600
13	Exclude patients who were treated with brachytherapy	26 747
14	Exclude patients who received <1 or >40 fractions of radiation therapy	26 163

* We used Surveillance, Epidemiology, and End Results–Medicare data to identify 65 820 Medicare beneficiaries diagnosed with a new cancer who reside within one of 16 geographic catchment areas representing approximately 26% of the US population.

Table 2. Claims codes used to classify billing types*

Treatment	ICD-9 procedure code	ICD-9 diagnosis code	CPT/HCPCS code	Revenue center code
Radiation therapy CPT codes	NA	NA	77371–77373, 77401–77525, 77761–77799, G0174	NA
Brachytherapy CPT codes	NA	NA	77326–77328, 77761–77799	NA
IMRT CPT/HCPCS codes	NA	NA	77418, G0174	NA
Total number of fractions of radiation therapy	NA	NA	77371–77373, 77401–77416, 77418, 77422, 77423, 77522–77525, G0174 (total number of times any of these codes appeared on separate days within 1 year of diagnosis)	NA
Breast-conserving surgery	85.2, 85.20, 85.21, 85.22, 85.23, or 85.25	NA	19110, 19120, 19125, 19126, 19160, or 19162, 19301, 19302	NA
Mastectomy	85.4, 85.41, 85.42, 85.43, 85.44, 85.45, 85.46, 85.47, 85.48	NA	19180, 19182, 19200, 19220, 19240, 19303, 19304, 19305, 19306, 19307	NA
Chemotherapy	99.25	V58.1, V66.2, V67.2	96400–96549, Q0083–Q0085, J8520, J8521, J8530, J8540, J8560, J8597, J8610, J8999; J9000–J9999 but excluding J9003, J9165, J9175, J9202, J9209, J9212–J9226, J9240, J9395	0331, 0332, 0335

* CPT = Common Procedural Terminology; HCPCS = Healthcare Common Procedural Coding System; ICD = *International Classification of Diseases*; IMRT = intensity-modulated radiation therapy, NA = not applicable.

Primary Outcome

The primary outcome was billing for at least one fraction of IMRT, which was defined as the appearance of a claim for delivery of a fraction of IMRT (CPT-4 code 77418 or Healthcare Common Procedure Coding System temporary code G0174, Table 2) within 1 year of breast cancer diagnosis. To submit a claim for code 77418, the treatment delivered must satisfy the criteria for delivery of IMRT as defined by the local coverage determination (LCD) rendered by the Medicare Fiscal Intermediary for part A claims and the Medicare Carrier for part B claims. These LCDs are specific to the region in which a patient lives and, during the study interval, varied substantially by region (24). We chose to focus our attention on the Carrier LCDs for IMRT because these directly govern physician reimbursement (Although there is no professional/physician reimbursement component for CPT 77418, other aspects of IMRT, such as IMRT treatment planning [CPT 77301], do have a professional component and are governed by the same LCD as 77418.). During the study period, three of the SEER registries were governed by Carriers that allowed forward or inverse planning to satisfy criteria for CPT 77418/77301 (Detroit, Atlanta, and rural Georgia [The LCD for the state of Georgia initially did not allow forward planning but was changed on August 15, 2005, to allow it.]), four SEER registries did not have specific Carrier LCDs regarding the definition of IMRT (Kentucky, Louisiana, New Mexico, and Utah), and nine SEER registries were governed by Carriers that required inverse planning to satisfy criteria for CPT 77418/77301 (all other registries) (24).

Treatment-Related Variables

Treatment with any radiation therapy was determined by the appearance of a claim for delivery of a radiation therapy fraction (CPT-4 codes 77371–77373, 77401–77416, 77418, 77422, 77423, 77522–77525 or the Healthcare Common Procedure Coding System code G0174, Table 2) within 1 year of breast cancer diagnosis. Patients were considered to have received chemotherapy if claims for any of the *International Classification of Diseases (ICD)-9* procedure or diagnosis codes, CPT-4 codes, or Revenue Center codes (Table 2) were present within 1 year of diagnosis. The type of breast surgery was determined by selecting the most extensive surgery reported by either SEER or Medicare billing claims within 9 months of diagnosis.

Health Services-Related Variables

The SEER registries were grouped into three categories on the basis of the Carrier LCD for IMRT active during the study interval (24). However, for two registries (Utah and Kentucky), there was no record of a Carrier LCD governing use of IMRT between 2001 and 2006, and as a result, we chose to use the Fiscal Intermediary LCD (governing part A claims) for these two registries. The “favorable” coverage group included registries for which breast IMRT was explicitly allowed throughout the study period (Atlanta, Detroit, and Rural Georgia). The “neutral” coverage group included registries for which the LCD did not mention IMRT (Louisiana and New Mexico) or, in the case of Kentucky, breast IMRT was prohibited in 2001–2003 and explicitly allowed in 2004–2005. The “unfavorable” coverage group included registries for which breast IMRT was either explicitly forbidden or only allowed in very unusual situations as justified in the medical record

(Connecticut, Greater California, Hawaii, Iowa, Los Angeles, New Jersey, San Francisco, San Jose, Seattle, and Utah).

Patients were considered to have received radiation therapy in a hospital-associated outpatient clinic if claims for delivery of radiation therapy were only present in the SEER–Medicare Outpatient data file. Patients were considered to have received radiation therapy in a freestanding radiation therapy center if claims for delivery of radiation were only present in the SEER–Medicare Carrier Claims file. Patients were considered to have received radiation therapy in both a hospital-associated outpatient clinic and a freestanding radiation therapy center if claims for delivery of radiation therapy were present in both the Outpatient and Carrier Claims files.

The number of radiation oncologists and general surgeons in the patient’s county of residence was determined using data from the Area Resource File for the years 2001–2005. The Area Resource File contains information on health facilities, health professions, measures of resource scarcity, health status, economic activity, health training programs, and socioeconomic and environmental characteristics. In addition, the basic file contains geographic codes and descriptors that enable it to be linked to many other files and to aggregate counties into various geographic groupings. We converted the number of radiation oncologists and general surgeons reported in the Area Resource File to the number in the patients’ health service area (HSA) of residence. A HSA is defined as “one or more counties that are relatively self-contained with respect to the provision of routine hospital care” and is used by the National Center for Health Statistics for geographic patterns of care analyses (25). The density of radiation oncologists and general surgeons per HSA was determined by dividing the number of radiation oncologists and general surgeons, respectively, by the population for a given HSA.

Patient- and Tumor-Related Variables

Patient characteristics included year of diagnosis, age at diagnosis (66 years and older), race (white, Hispanic, black, Asian, and unknown), marital status (married, unmarried, and unknown) (26,27), SEER registry, median income of census tract or zip code (quartile or unknown) (28), and percent adults in census tract or zip code with at least some college education (quartile or unknown) (Table 3). A modified Charlson comorbidity index (29–31) was calculated using claims spanning an interval of 12 months to 1 month before diagnosis. To enhance specificity, Medicare part B diagnosis codes were only considered in the comorbidity index if they appeared more than once over a time interval exceeding 30 days (32,33). If patients did not access or encounter the medical system in the year preceding diagnosis, then no claims were present and such patients were classified as having “unknown” comorbidity. Tumor characteristics as reported by SEER include size, grade, nodal status, laterality, estrogen receptor status, histology, and behavior (invasive vs in situ) (23). Histology was coded as ductal, lobular, or other/unknown (23). Margin status and lymph-vascular space invasion are not reported by SEER.

Cost of Radiation Therapy

The total cost of care and the cost of radiation therapy were calculated from a payer’s perspective (total amount reimbursed by Medicare to providers) for a window of time spanning from 15 days before the diagnosis date to 1 year after the diagnosis date. Costs were

adjusted for inflation and normalized to the year 2005 (the final year of our study) using the Prospective Pricing Index for part A claims and the Medicare Economic Index for part B claims, in accordance with prior methods (34,35). Costs were also adjusted for geographic variation using the geographic adjustment factor for part A claims and the geographic practice cost index for part B claims, in accordance with prior methods (34,35). All adjusters were provided by the National Cancer Institute’s Health Services and Economics Branch of the Applied Research Program. Total costs included Medicare payment aggregated from claims in the Medicare Provider Analysis and Review (inpatient), Outpatient (hospital-based outpatient), and Carrier Claims (individual physician) files. Radiation therapy and related costs were calculated in accordance with prior methods by summing the costs of claims occurring in the Outpatient and Carrier Claims files that included a CPT code between 77261 and 77999 (35). Mean total costs and mean radiation-related costs were reported by year and by type of radiation therapy (IMRT vs non-IMRT).

Statistical Analysis

Bivariate associations between covariates and billing for IMRT were tested using Pearson χ^2 . For all analyses, age was categorized in 5-year increments; comorbidity was classified as none (Charlson score = 0), mild (Charlson score = 1), or moderate to severe (Charlson score ≥ 2); tumor size and nodal status were categorized according to cut points used by the American Joint Commission on Cancer staging system (36); and the following continuous variables were subdivided into quartiles: median income, adults with college education, radiation oncologist density, and surgeon density. The impact of individual covariates on cost of treatment was assessed using the Wilcoxon two-sample test. The 95% confidence interval (CI) around the difference in cost between two treatment groups was determined using a nonparametric bootstrap with 1000 samples (37). Covariates associated with billing for IMRT at *P* less than or equal to .10 were then included in a multivariable logistic regression model, with unknown values entered as dummy variables of a separate category. Odds ratios (ORs) were calculated because the event of interest was relatively rare with less than 10% of patients in the cohort receiving IMRT. For analysis of geographic variation within the multivariable model, Greater California was chosen as the referent group because it was the largest registry during the study interval. Goodness of fit was assessed using the Hosmer and Lemeshow test, in which a *P* value greater than .05 indicates an acceptable fit. All statistical analyses were two-sided using an alpha level equal to .05 and were conducted using SAS version 9.2 (SAS Institute, Inc., Cary, NC). In accordance with policy regarding use of the SEER–Medicare data, the precise percentage is not reported to protect confidentiality for sample sizes less than 11. This study used de-identified data and was exempted from review by the University of Texas M. D. Anderson Cancer Center Institutional Review Board.

Results

Demographic, Health Services, Tumor, and Treatment Characteristics

In this cohort of 26 163 women aged 66 years and older and treated with radiation for nonmetastatic breast cancer, median age

Table 3. Associations between billing for intensity-modulated radiation therapy (IMRT) and demographic, health services, tumor, and treatment characteristics*

Characteristic	No.	Percentage treated with any IMRT	P
Entire cohort	26 163	6.0	
Demographics			
Year of diagnosis			<.001
2001	5196	0.9	
2002	5273	3.1	
2003	5369	5.7	
2004	5305	9.2	
2005	5020	11.2	
Age, y			.013
66–69	6459	6.8	
70–74	7789	5.8	
75–79	6798	6.0	
≥80	5117	5.4	
Race			<.001
White	23 337	6.0	
Hispanic	268	<4.1	
Black	1589	7.6	
Asian	494	2.8	
Others/unknown	475	3.2	
Marital status			<.001†
Married	13 005	5.9	
Unmarried (separated, divorced, or widowed)	12 450	5.4	
Unknown	708	18.4	
SEER registry (LCD type)			<.001
Atlanta and rural Georgia‡ (favorable)	819	22.6	
Connecticut (unfavorable)	2108	1.5	
Detroit (favorable)	2047	23.1	
Greater California (unfavorable)	4950	2.7	
Hawaii (unfavorable)	422	3.1	
Iowa (unfavorable)	1516	1.1	
Kentucky (neutral)	1749	8.5	
Los Angeles (unfavorable)	1903	2.3	
Louisiana (neutral)	1498	4.9	
New Jersey (unfavorable)	4757	7.8	
New Mexico (neutral)	521	12.3	
San Francisco§ (unfavorable)	903	<1.2	
San Jose§ (unfavorable)	636	<1.7	
Seattle (unfavorable)	1634	<0.7	
Utah§ (unfavorable)	700	<1.6	
Comorbidity index			.028
0	15 280	5.9	
1	6413	5.7	
≥2	3807	6.9	
Unknown	663	4.5	
Median income in census tract or zip code			.004
Lowest quartile	6540	5.4	
Second quartile	6540	5.5	
Third quartile	6540	6.4	
Highest quartile	6540	6.7	
Unknown	<11	0.0	
Adults in census tract or zip code with at least some college education			.549
Lowest quartile	6540	6.1	
Second quartile	6540	6.2	
Third quartile	6530	5.6	
Highest quartile	6540	6.0	
Unknown	<11	0.0	
Health services characteristics			<.001
No. of radiation oncologists in HSA/population of HSA¶			
Lowest quartile	833	3.4	
Second quartile	2734	3.1	
Third quartile	9184	4.6	

(Table continues)

Table 3 (Continued).

Characteristic	No.	Percentage treated with any IMRT	P
Highest quartile	13 412	7.7	
No. of general surgeons in HSA/population of HSA¶			<.001
Lowest quartile	1801	2.3	
Second quartile	3504	3.3	
Third quartile	6918	3.4	
Highest quartile	13 940	8.4	
Medicare local coverage determination			<.001
Favorable toward breast IMRT	2866	22.9	
Neutral toward breast IMRT	3768	7.6	
Unfavorable toward breast IMRT	19 529	3.2	
Type of radiation therapy treatment center			<.001
Hospital-based outpatient center	18 165	5.4	
Freestanding center	7689	7.6	
Both	317	<3.5	
Tumor characteristics			
Tumor size, cm			<.001
<2.0	16 450	6.4	
2.0–≤5.0	6474	5.30	
≥5.0	999	3.60	
Unknown/not applicable	2240	5.8	
Tumor histology			.013
Ductal	17 537	5.9	
Lobular	2235	4.8	
Other/unknown	6391	6.5	
Estrogen receptor status			.028
Positive	18 258	6.1	
Negative/borderline	3207	6.4	
Unknown	4698	5.2	
Positive nodes, No.			<.001
0: all nodes examined are negative	14 809	6.50	
1–3	3555	4.80	
≥4	1993	3.30	
No nodes examined/not specified/unknown	5806	6.50	
Laterality			<.001#
Left	13 230	6.5	
Right	12 930	5.5	
Bilateral/unknown	<11	0.0	
Treatment characteristics			
Type of surgery			<.001
Breast-conserving surgery	22 676	6.5	
Mastectomy	3487	2.8	
Receipt of chemotherapy			.101
No	20 573	6.1	
Yes	5590	5.5	

* “Unfavorable” refers to Medicare carrier LCDs that did not generally permit breast IMRT during the study interval. “Neutral” refers to Medicare LCDs that either did not specify policy regarding breast IMRT or, in the case of Kentucky, did not permit breast IMRT from 2001 to 2003 but did permit breast IMRT in 2004–2006. “Favorable” refers to Medicare LCDs that allowed breast IMRT (see “Methods” for further detail). All *P* values were calculated by using two-sided Pearson χ^2 test. HSA = health service area, IMRT = intensity-modulated radiation therapy, LCD = local coverage determination.

† *P* = .045 if unknown marital status is excluded.

‡ Atlanta and Rural Georgia registries were combined because of geographic proximity and small sample size in rural Georgia (N = 42).

§ San Francisco, San Jose, and Utah were combined for calculation of the χ^2 *P* value because the total number of patients in these registries who received radiation was less than 11.

|| Cell sizes have been rounded to only three significant digits to protect confidentiality of the unknown group.

¶ The unit of analysis for determining quartiles of radiation oncologist and surgeon density was the HSA, not the patient. Accordingly, patients are not equally distributed across these HSA-based quartiles.

The bilateral/unknown group was excluded from the calculation of this χ^2 statistic because its cell size is less than 11.

was 74 years (interquartile range = 70–79 years), 89% were white, 69% received radiation therapy at a hospital-affiliated outpatient clinic, 57% were pathologically node negative, and 87% were treated with breast-conserving surgery (Table 3). A claim for

IMRT was present in a total of 1567 (6%) patient Medicare claims records. Billing for IMRT increased from 0.9% (49 of 5196) of patients diagnosed in 2001 to 11.2% (564 of 5020) of patients diagnosed in 2005. IMRT billing was adopted more quickly for

patients treated with breast-conserving surgery as compared with mastectomy ($P < .001$, Figure 1, A), patients treated in freestanding centers as compared with hospital-based outpatient centers ($P < .001$, Figure 1, B), and patients living in regions with a Carrier LCD favorable to breast IMRT as compared with regions with neutral or unfavorable LCDs ($P < .001$, Figure 1, C).

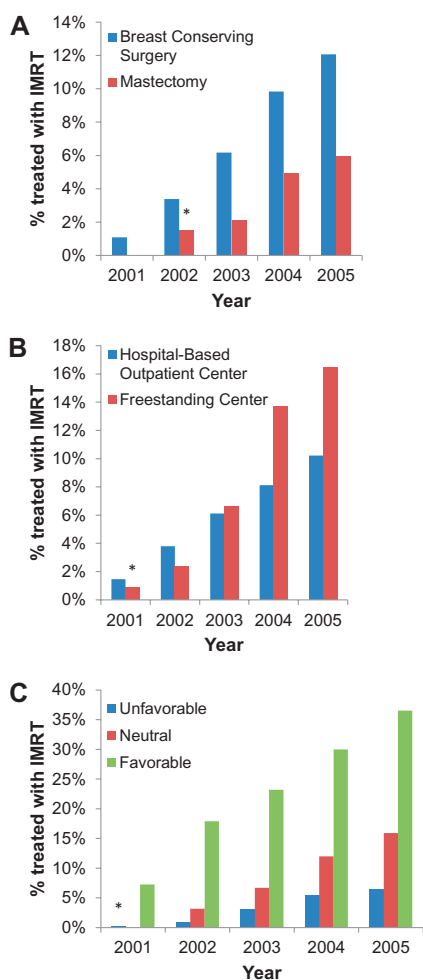


Figure 1. Utilization of intensity-modulated radiation therapy (IMRT) billing by type of surgery, treatment center, and Medicare carrier local coverage determination (LCD), 2001–2005. **A)** IMRT billing by type of surgery. Variation in IMRT billing by type of surgery was statistically significant at P less than .001 (two-sided Pearson χ^2). As indicated by the **asterisk**, the percentage of patients undergoing mastectomy in 2002 who received IMRT is actually less than reported in this figure, but the precise percentage is not reported to protect confidentiality for sample sizes less than 11. **B)** IMRT billing by type of treatment center. Variation in IMRT billing by type of treatment center was statistically significant at P less than .001 (two-sided Pearson χ^2). As indicated by the **asterisk**, the percentage of patients treated at a freestanding center in 2001 who received IMRT is actually less than reported in this figure, but the precise percentage is not reported to protect confidentiality for sample sizes less than 11. Patients treated with mastectomy are excluded from this figure because use of IMRT was statistically significantly lower in patients undergoing mastectomy as compared with breast-conserving surgery [see Table 3 and (A)]. **C)** IMRT billing by Medicare carrier LCD. “Unfavorable” refers to Medicare carrier LCDs that did not generally permit breast IMRT during the study interval. “Neutral” refers to Medicare LCDs that either did not specify policy regarding breast IMRT or, in the case of Kentucky, did not permit breast IMRT from 2001 to 2003 but did permit breast IMRT in 2004–2006. “Favorable” refers to Medicare LCDs that allowed breast IMRT. Variation in utilization between the three different coverage determination groups was statistically significant at P less than .001 (two-sided Pearson χ^2). As indicated by the **asterisk**, the percentage of patients residing in a region with unfavorable coverage in 2001 who received IMRT is actually less than reported in this figure, but the precise percentage is not reported to protect confidentiality for sample sizes less than 11.

.001, Figure 1, B), and patients living in regions with a Carrier LCD favorable to breast IMRT as compared with regions with neutral or unfavorable LCDs ($P < .001$, Figure 1, C).

Predictors of IMRT Use: Multivariable Model

A multivariable logistic model identified multiple predictors for IMRT billing (goodness of fit $P = .20$; area under the receiver operator curve = 0.86) (Table 4). As expected, IMRT billing increased substantially with year of diagnosis. Billing for IMRT varied substantially among the various SEER registries, with lowest use in Seattle (OR = 0.15, 95% CI = 0.07 to 0.33; $P < .001$) and highest use in Atlanta (OR = 12.45, 95% CI = 9.25 to 16.75; $P < .001$), as compared with the referent group of Greater California. With regard to health services characteristics, IMRT billing was more likely for patients living in a HSA with the highest quartile of radiation oncologist density (OR = 2.32, 95% CI = 1.47 to 3.68; $P < .001$) as compared with patients living in a HSA with the lowest quartile of radiation oncologist density. Billing for IMRT was also more likely for patients treated at a freestanding radiation therapy center (OR = 1.36, 95% CI = 1.20 to 1.53; $P < .001$) as compared with a hospital-based outpatient center. With regard to tumor characteristics, IMRT billing was more likely for left-sided tumors (OR = 1.30, 95% CI = 1.16 to 1.45; $P < .001$) as compared with right-sided tumors. With regard to treatment characteristics, IMRT billing was less likely for patients treated with mastectomy (OR = 0.39, 95% CI = 0.30 to 0.50; $P < .001$) as compared with patients treated with breast-conserving surgery.

Given the widespread geographic variation, we created a second multivariable model to determine if the Medicare Carrier LCD regarding IMRT predicted billing for IMRT. After adjusting for all covariates in Table 4 with the exception of SEER registry, we found that, as compared with the group for which local coverage of breast IMRT was unfavorable, IMRT billing was higher for the neutral coverage group (OR = 3.34, 95% CI = 2.81 to 3.96; $P < .001$) and highest for the favorable coverage group (OR = 10.87, 95% CI = 9.26 to 12.76; $P < .001$).

Cost of Radiation Therapy

The mean cost of radiation therapy within the first year of diagnosis was \$7179 for non-IMRT patients and \$15 230 for IMRT patients (difference = \$8051, 95% CI = \$7742 to \$8375; $P < .001$). The mean total cost of all health care within the first year of diagnosis was \$21 674 for non-IMRT patients and \$29 366 for IMRT patients (difference = \$7692, 95% CI = \$6911 to \$8523; $P < .001$). Within the first year of diagnosis, therefore, radiation-related costs accounted for 33% of total medical care costs for non-IMRT patients and 52% of total medical care costs for IMRT patients. Between 2001 and 2005, mean radiation-related costs increased by 21% for non-IMRT patients (from \$6281 to \$7591), by 30% for IMRT patients (from \$11 852 to \$15 442), and by 33% for all patients combined (from \$6334 to \$8473) (Figure 2, A and B). Between 2001 and 2005, mean total costs of medical care during the first year following diagnosis rose in a manner similar to radiation-related costs, as radiation-related costs were a major contributor to total costs. Total costs increased by 23% for non-IMRT patients (from \$19 468 to \$23 875), by 33% for IMRT patients (from \$22 749 to \$30 194), and by 26% for all patients combined (from \$19 499 to \$24 585) (Figure 3, A and B).

Table 4. Predictors of billing for intensity-modulated radiation therapy (IMRT): multivariable model*

Predictor	OR (95% CI)	P
Demographics		
Year of diagnosis		
2001	1 (referent)	
2002	3.53 (2.54 to 4.90)	<.001
2003	7.10 (5.2 to 9.69)	<.001
2004	12.28 (9.06 to 16.66)	<.001
2005	15.81 (11.67 to 21.43)	<.001
Age, y		
66–69	1 (referent)	
70–74	0.81 (0.7 to 0.94)	.007
75–79	0.86 (0.74 to 1.01)	.06
≥80	0.82 (0.69 to 0.98)	.03
Race		
White	1 (referent)	
Hispanic	0.94 (0.47 to 1.89)	.86
Black	0.60 (0.48 to 0.76)	<.001
Asian	0.83 (0.46 to 1.52)	.55
Others/unknown	0.82 (0.45 to 1.48)	.51
Marital status		
Married	1 (referent)	
Unmarried	0.9 (0.8 to 1.01)	.08
Unknown	2.08 (1.64 to 2.64)	<.001
SEER registry (LCD type)		
Greater California (unfavorable)	1 (referent)	
Atlanta and rural Georgia (favorable)	12.45 (9.25 to 16.75)	<.001
Detroit (favorable)	11.27 (8.6 to 14.76)	<.001
Connecticut (unfavorable)	0.51 (0.34 to 0.79)	.002
Utah, San Francisco, and San Jose (unfavorable)	0.16 (0.08 to 0.3)	<.001
Hawaii (unfavorable)	1.37 (0.69 to 2.73)	.37
Iowa (unfavorable)	0.48 (0.28 to 0.81)	.006
Kentucky (neutral)	3.75 (2.86 to 4.93)	<.001
Los Angeles (unfavorable)	0.73 (0.5 to 1.06)	.10
Louisiana (neutral)	2.4 (1.75 to 3.3)	<.001
New Jersey (unfavorable)	2.94 (2.3 to 3.76)	<.001
New Mexico (neutral)	7.21 (5.02 to 10.36)	<.001
Seattle (unfavorable)	0.15 (0.07 to 0.33)	<.001
Comorbidity		
0	1 (referent)	
1	0.90 (0.79 to 1.04)	.15
≥2	1.00 (0.85 to 1.17)	.96
Unknown	0.95 (0.63 to 1.42)	.80
Median income in census tract or zip code		
Lowest quartile	1 (referent)	
Second quartile	0.96 (0.81 to 1.14)	.64
Third quartile	0.93 (0.78 to 1.11)	.44
Highest quartile	1.0 (0.83 to 1.2)	.99
Health services characteristics		
No. of radiation oncologists in HSA/population of HSA		
Lowest quartile	1 (referent)	
Second quartile	1.20 (0.76 to 1.92)	.43
Third quartile	2.02 (1.28 to 3.2)	.003
Highest quartile	2.32 (1.47 to 3.68)	<.001
No. of general surgeons in HSA/population of HSA		
Lowest quartile	1 (referent)	
Second quartile	1.33 (0.9 to 1.98)	.15
Third quartile	1.47 (0.99 to 2.18)	.054
Highest quartile	1.45 (0.98 to 2.16)	.07
Type of radiation therapy treatment center		
Hospital-based outpatient	1 (referent)	
Freestanding center	1.36 (1.2 to 1.53)	<.001

(Table continues)

Table 4 (Continued).

Predictor	OR (95% CI)	P
Both	0.44 (0.17 to 1.1)	.08
Tumor characteristics		
Tumor size, cm		
<2.0	1 (referent)	
2.0–<5.0	0.96 (0.83 to 1.11)	.61
≥5.0	0.97 (0.66 to 1.44)	.88
Unknown/not applicable	0.93 (0.75 to 1.17)	.56
Tumor histology		
Ductal	1 (referent)	
Lobular	0.94 (0.76 to 1.18)	.61
Other/unknown	1.15 (1.01 to 1.31)	.036
Estrogen receptor status		
Positive	1 (referent)	
Negative/borderline	1.08 (0.91 to 1.28)	0.4
Unknown	1.03 (0.87 to 1.22)	.72
No. of positive nodes		
0	1 (referent)	
1–3	0.82 (0.68 to 0.99)	.038
≥4	0.77 (0.57 to 1.04)	.09
No nodes examined/not specified/unknown	0.85 (0.73 to 0.98)	.03
Laterality		
Right	1 (referent)	
Left	1.30 (1.16 to 1.45)	<.001
Treatment characteristics		
Type of surgery		
Breast-conserving surgery	1 (referent)	
Mastectomy	0.39 (0.3 to 0.5)	<.001

* The total number of case patients excludes patients with unknown income status and/or unknown/bilateral laterality, yielding 26 148 case patients for the final analytic sample. “Unfavorable” refers to Medicare carrier LCDs that did not generally permit breast IMRT during the study interval. “Neutral” refers to Medicare LCDs that either did not specify policy regarding breast IMRT or, in the case of Kentucky, did not permit breast IMRT from 2001 to 2003 but did permit breast IMRT in 2004–2006. “Favorable” refers to Medicare LCDs that allowed breast IMRT (see “Methods” for further detail). All *P* values were calculated using multivariable logistic regression. All statistical tests were two-sided. CI = confidence interval; HSA = health service area; IMRT = intensity-modulated radiation therapy; LCD = local coverage determination; OR = odds ratio.

In addition, we found that mean radiation-related costs within the first year of diagnosis were 28% higher (\$9451 vs \$7391; difference = \$2060, 95% CI = \$1900 to \$2225; *P* < .001) for patients residing in regions with Medicare Carrier LCDs favorable toward breast IMRT as compared with those residing in regions with LCDs unfavorable toward breast IMRT (Figure 4). Similarly, total health-care costs within the first year of diagnosis were 12% higher (\$24 259 vs \$21 696; difference = \$2563, 95% CI = \$1979 to \$3198; *P* < .001) for patients residing in regions with Medicare Carrier LCDs favorable toward breast IMRT as compared with those residing in regions with LCDs unfavorable toward breast IMRT (Figure 4). For patients treated with IMRT, mean per patient radiation-related costs within the first year of diagnosis were \$21 488 for patients treated at freestanding centers compared with \$11 496 for patients treated at hospital-based outpatient clinics (difference = \$9992, 95% CI = \$9535 to \$10 423; *P* < .001). Similarly, for patients treated with IMRT, mean total costs within the first year of diagnosis were \$36 075 for patients treated at freestanding centers compared with \$25 330 for patients treated at hospital-based centers (difference = \$10 745, 95% CI = \$9260 to \$12 148; *P* < .001).

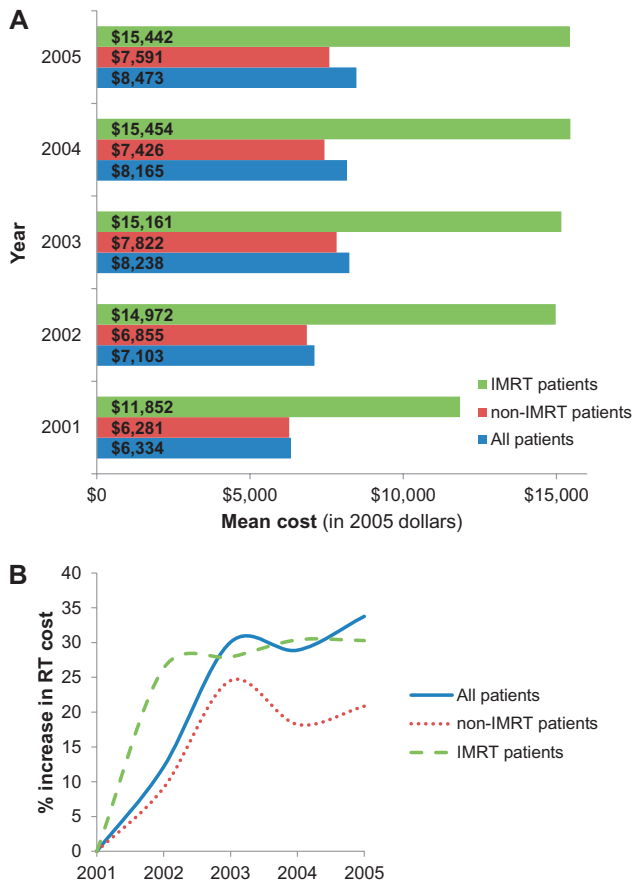


Figure 2. Mean per patient radiation-related treatment cost and percent change in cost by year and type of radiation: **A)** Mean radiation-related treatment cost. **B)** Percentage increase in mean radiation-related treatment cost. Costs include all Medicare reimbursements to providers for radiation therapy-related claims from 15 days before diagnosis to 1 year after diagnosis, are normalized to 2005 dollars, and are adjusted for geographic variation in Medicare reimbursement. IMRT = intensity-modulated radiation therapy.

Discussion

In this population-based study of older women with primary non-metastatic breast cancer treated with radiation therapy between 2001 and 2005, we found that billing for IMRT treatment delivery increased more than 10-fold. This sharp increase suggests that during this time more patients gained access to the potential benefits of IMRT with respect to its ability to minimize acute dermatitis and optimize long-term cosmetic outcome (10,11). Our findings also help to identify factors that appear to have either promoted or discouraged adoption of billing for IMRT. Specifically, the Medicare Carrier LCDs powerfully influenced adoption, with use of IMRT billing more than fivefold higher in regions with coverage favorable toward breast IMRT as compared with regions with coverage unfavorable toward breast IMRT. Furthermore, use of IMRT billing was 36% higher for patients treated in freestanding radiation centers as compared with patients treated in hospital-based outpatient clinics. These findings suggest that reimbursement policy and practice setting strongly influenced adoption of IMRT billing for breast cancer.

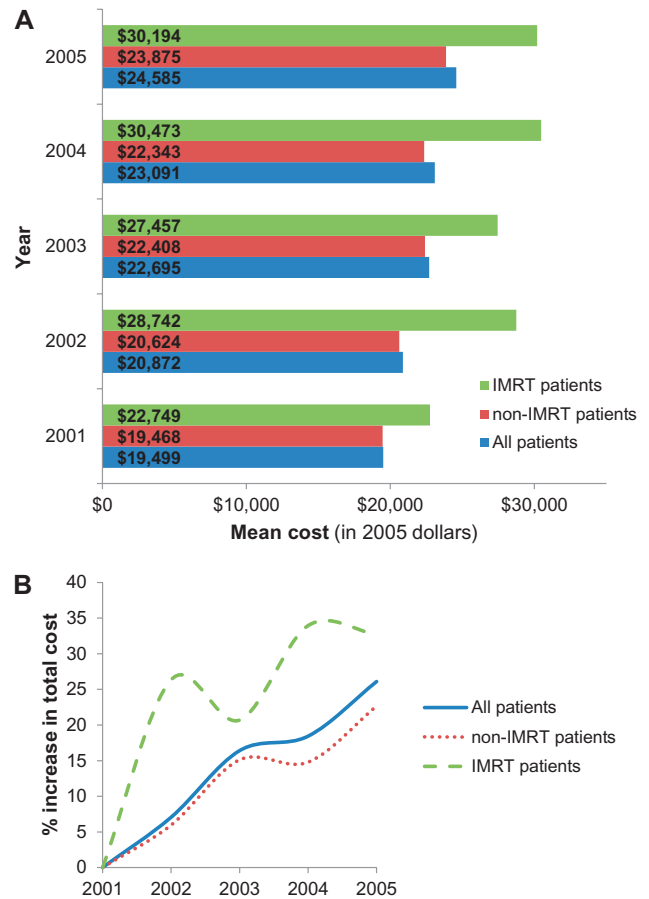


Figure 3. Mean per patient total health-care costs and percent change in total health-care costs by year and type of radiation: **A)** Mean total health-care costs. **B)** Percentage increase in mean total health-care costs. Costs include all Medicare reimbursements to providers from 15 days before diagnosis to 1 year after diagnosis, are normalized to 2005 dollars, and are adjusted for geographic variation in Medicare reimbursement. IMRT = intensity-modulated radiation therapy.

Our cost analysis indicates that, after adjusting for medical inflation, the mean per patient cost of radiation therapy for breast cancer increased by 33% between 2001 and 2005; among non-IMRT patients, the cost increase was 21%. Adoption of the IMRT billing code appears to have accelerated growth in the cost of radiation therapy both because IMRT is reimbursed more favorably than non-IMRT and because the cost of IMRT is growing faster than the cost of non-IMRT. Looking to years subsequent to 2005, continued increases in utilization of the IMRT billing code could lead to a further escalation in the cost of radiation therapy. For example, our data suggest that if 50% of patients were treated with IMRT, then the average cost of radiation per patient would be 80% higher than the baseline per patient cost of radiation in 2001 (assuming the cost of IMRT remained at 2005 levels). Furthermore, our data indicate that Medicare LCDs can exert a strong influence over cost because the mean cost of radiation per patient within the first year of diagnosis was 28% higher in regions with coverage favorable toward breast IMRT as compared with regions with coverage unfavorable toward breast IMRT. Finally, our data

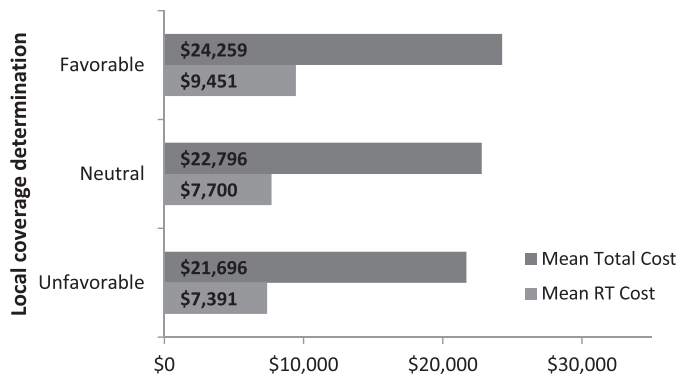


Figure 4. Comparison of radiation-related and total health-care costs within 1 year of diagnosis by type of local coverage determination (LCD). Mean per patient radiation-related and total health-care costs within 1 year of diagnosis were the highest for patients residing in areas with a Medicare LCD favorable toward breast intensity-modulated radiation therapy (IMRT) and lowest for patients residing in areas with a Medicare LCD unfavorable toward breast IMRT ($P < .001$ for both radiation-related costs and total costs, two-sided Wilcoxon two-sample test).

illuminate a nearly twofold differential in reimbursement for IMRT between freestanding centers and hospital-based outpatient clinics, indicating that certain variation in cost is endogenous to the current Medicare reimbursement structure and may have contributed to the differential adoption rates of IMRT in freestanding vs hospital-based outpatient centers.

In general, three-dimensional modulation of the radiation beam profile in the treatment of breast cancer can be achieved using two different approaches. The first, referred to herein as “field-in-field (FiF) forward planning,” is relatively straightforward to implement and entails creation of one or more subfields within the initial radiation field to improve homogeneity of the delivered radiation dose. The second, referred to herein as “inverse planning,” generally requires a greater degree of physician and treatment planning time to contour target volumes and critical structures, implement an intensity modulation beam optimization algorithm, iteratively evaluate and modify the plan, and perform quality assurance to verify the dose delivered. For most Medicare Carriers, inverse planning is a prerequisite for IMRT billing. In the pivotal randomized trial (10) that compared intensity-modulated whole-breast irradiation to standard two-dimensional whole-breast irradiation, both forward-planned FiF intensity modulation and inverse-planned IMRT were used depending on the center at which the patient was treated (10). This trial was conducted in Canada, where the distinction between the two techniques had no reimbursement implications. With respect to the primary endpoint of acute radiation-induced dermatitis, both techniques appear to have yielded a similar benefit. The investigators also conducted a dosimetric study (16) comparing forward planning to inverse planning and concluded that although inverse-planned IMRT conferred a marginal improvement in the volume of breast tissue receiving greater than 110% of the prescription dose, the dose to the inframammary fold was similar for the two techniques. The authors concluded that it is unlikely that inverse planning would confer a meaningful clinical benefit over forward planning with respect to the endpoint of acute radiation-induced dermatitis

(16). Despite the apparent similarity in clinical outcomes with forward vs inverse planning noted in this trial, it nevertheless remains possible that inverse-planned IMRT may improve certain outcomes by reducing the dose to the heart and lung, and prospective investigations along these lines are ongoing.

Despite the proven benefits of FiF forward planning, there is currently lack of consensus regarding whether such treatment should be considered IMRT for the purposes of billing and reimbursement. Notably, some treatment centers that use FiF forward planning do not bill for IMRT delivery, and the majority of Medicare Carriers do not allow billing for IMRT delivery for FiF forward planning (24). As a result, for many centers the cost of a course of FiF forward-planned intensity-modulated whole-breast irradiation would be only slightly higher than the mean cost of non-IMRT (\$7179) reported in this study (FiF forward planning may entail some extra charges because of the need for three-dimensional planning and dosimetric calculations for multiple subfields.). In contrast, in regions where FiF forward planning meets billing criteria for IMRT, the cost of FiF forward planning would be approximately \$11 496 at hospital-based outpatient centers and \$21 487 at freestanding centers. This type of geographic variation in Medicare payments has been previously cited, both in the lay press and in health policy circles (21,38), as a potential source of waste within the Medicare system. Our data suggest that with respect to breast radiation therapy much of the variation in cost can be directly attributed to inconsistent treatment definitions and reimbursement rates authorized by Medicare and its intermediaries.

Promotion of value, which is defined as the ratio of quality to cost, has received greater attention as the recently passed Patient Protection and Affordable Care Act (PPACA) called for study of new reimbursement models that reward efficiency and value in medical care (21). When applied to breast radiation therapy, our data illustrate that the current reimbursement system is structured to either control cost, as in the regions with unfavorable coverage for breast IMRT, or to promote quality, as in the regions that allow billing IMRT charges for patients with breast cancer. Although current reimbursement policy does not prohibit the use of FiF forward planning in regions where such treatment is not billed as IMRT, its use is currently not incentivized or even reported. There is a need for novel reimbursement strategies that simultaneously incentivize the implementation of clinically important methods that improve three-dimensional dose distributions and reduce toxicity while promoting use of the most cost-effective method. The inherently regional nature of LCDs offers the opportunity to enact, study, and compare different policies in different regions in an effort to identify optimal policy solutions. Specific policies that could promote value may include creation of quality measures that encourage use of FiF forward-planned whole-breast irradiation, akin to the Practice Quality Reporting Initiative (PQRI) (39), or tying reimbursement more closely to achieving the goals of radiation treatment planning.

Regarding other factors predictive of use of the billing code for IMRT, our finding that IMRT was used more frequently for patients treated with breast-conserving surgery than mastectomy is consistent with the published literature that primarily evaluated IMRT in the setting of breast-conserving surgery (10,11). Outside

a clinical trial, caution may be needed in the application of IMRT to the postmastectomy setting because the relatively thin nature of the chest wall could preclude accurate inverse planning and dose-volume analysis. Our finding that IMRT was used more frequently for left- than right-sided breast cancers may reflect the potential benefits suggested in the dosimetric literature of decreased cardiac irradiation with IMRT (8,9), although other non-IMRT strategies may offer superior cardiac protection (40,41). Finally, our finding of an association between density of radiation oncologists and increased use of IMRT may reflect competitive pressures that spur adoption of new technologies or possible financial pressures associated with practicing in a relatively saturated market.

Our study has several limitations. First, because FiF forward-planned intensity modulation does not have a unique CPT code, we were unable to determine to what extent patients were treated with FiF forward planning as compared with inverse planning techniques. This shortcoming of current CPT coding limits the ability of subsequent population-based studies to determine if actual use of IMRT is associated with improved clinical outcomes. Second, our cohort was limited to older women who were Medicare beneficiaries, and it remains possible that younger women may receive IMRT more frequently because of concerns regarding late toxic effects or because of insurance coverage issues. Third, our definition of IMRT was exclusively determined by a claim for delivery of an IMRT fraction, and this approach has not been previously validated when compared with the gold standard of chart review, although Medicare claims are generally thought to be accurate because they are tied to physician payment (42). Finally, our cost analysis was conducted from a payer's perspective and thus does not consider patient co-payments or coinsurance and also may not accurately reflect cost of radiation therapy for patients with private insurance. Furthermore, the payer's (Medicare) cost determined in this study may not reflect the actual cost of providing radiation therapy. This limitation is particularly relevant, given our finding that radiation therapy delivered with FiF forward planning was reimbursed at much higher rates in regions with favorable LCDs as compared with regions with unfavorable LCDs, despite the fact that the cost of providing this treatment should be similar in all regions regardless of LCD status.

In summary, the development of three-dimensional modulation of the radiation beam profile has led to a major advance in the treatment of breast cancer with respect to lowering risks of both acute and late toxic effects associated with radiation therapy (10,11). For patients treated at freestanding centers or residing in regions with a favorable LCD, Medicare reimbursement policy has helped to improve the quality of breast radiation by incentivizing adoption of three-dimensional dose modulation in the form of IMRT. However, for patients treated in regions with unfavorable LCDs, Medicare reimbursement policy has generally served to control cost, and it is not known to what extent physicians in these regions sought out less expensive yet comparable alternatives to IMRT such as FiF forward planning to achieve three-dimensional modulation of the radiation dose. Given our finding that current Medicare policy serves to promote quality in some regions while controlling cost in others, more research is needed to develop reimbursement models that reward value in the delivery of radiation therapy by promoting quality while controlling cost.

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