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Patterns and Correlates of Local Therapy for Women With Ductal Carcinoma-In-Situ

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Abstract

Purpose—Concerns have been raised about the quality of treatment for women with ductal carcinoma-in-situ (DCIS) because persistent high rates of mastectomy suggest overtreatment, whereas lower than expected rates of radiation therapy after breast-conserving surgery (BCS) suggest undertreatment.

Patients and Methods—All women with DCIS diagnosed in 2002 and who reported to the Detroit and Los Angeles Surveillance, Epidemiology, and End Results (SEER) registries were identified and surveyed shortly after receipt of surgery (response rate, 79.7%; n = 817). Analyses were restricted to patients with DCIS (n = 659) indicated by SEER stage data.

Results—Only 14.0% of patients at lowest risk of recurrence (based on tumor size and histologic grade) received a mastectomy compared with 22.8% and 52.6% of patients at intermediate and highest risk ($P < .001$). Only 13.1% of patients who were not influenced or slightly influenced by concerns about recurrence received mastectomy compared with 48.8% of women who were greatly influenced by this concern ($P < .001$). A between-geographic site difference in receipt of radiation after BCS was observed for the lowest risk group (38.9% in Los Angeles *v* 70.5% in Detroit) but not for the highest risk group (80.2% in Los Angeles *v* 85.9% in Detroit, $P = .006$ for site and risk group differences). Between-site differences in receipt of radiation after BCS were consistent with patient recall of surgeon discussions about treatment.

Conclusion—Surgeons are tailoring their recommendations for local therapy options for DCIS based on important clinical factors. Patient attitudes also play an important role in treatment decisions. The substantial influence of both surgeon opinion and patient attitudes should temper concerns about the quality of treatment for women with DCIS.

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INTRODUCTION

In the past decade, ductal carcinoma-in-situ (DCIS) has become a common clinical problem.[1–5] Long-term survival rates for DCIS are high, regardless of which type of treatment is received.[6,7] However, the risk of local recurrence after breast-conserving surgery (BCS) is a common concern because many recurrences among DCIS patients are invasive.[4,5,7–9] Local recurrence rates reported in the literature vary based on several factors including type of local treatment, the size and histologic grade of the tumor, and patient age.[10–14] Margins that are not free of tumor are also associated with an increased risk of local recurrence,[13,14] but the inability to obtain negative margins is recognized as an indication for mastectomy.[15] Recurrence rates after mastectomy have ranged from 1% to 2% at 10 years for DCIS lesions of all sizes and histologies.[15] Local recurrence rates of 8% to 23% at up to 12 years of follow-up have been reported for women who received BCS with radiation, whereas local recurrence rates of up to 30% have been reported for women who received BCS alone.[7,16–18]

Controversy exists regarding recommendations for surgical and radiation therapy for women with DCIS. Some investigators and policy makers have suggested that mastectomy is overtreatment for a disease with an extremely high survival rate and low absolute risk of recurrence.[6,8,15,17,19,20] Furthermore, some clinicians have argued that the marginal benefit of radiation in low-risk patients is not sufficient to justify the side effects of therapy.[17,21] Concerns have been raised about the quality of treatment for women with DCIS because studies have shown substantial geographic variation in the type of surgery performed and the use of adjuvant radiation therapy across the United States.[1,2,19]

Decisions about surgical and radiation therapy are made primarily by women and their surgeons [21A–23] because many women do not see a radiation or medical oncologist before making decisions about local therapy.[24,25] Therefore, variations in treatment patterns may reflect variations in surgeon recommendations as well as patient preferences for different treatment options.[24]

To address patterns and correlates of local therapy, we conducted a population-based survey of women with DCIS diagnosed in 2002 in the Los Angeles and Detroit metropolitan areas. The study questions were as follows: (1) what clinical factors are associated with the use of different surgical treatment options (mastectomy *v* BCS) and radiation after BCS?; (2) do characteristics of patient-surgeon communication explain variations in treatment across clinical risk groups?; and (3) do patient attitudes and preferences explain variations in treatment?

PATIENTS AND METHODS

Study Population

Women aged 79 years and younger diagnosed with DCIS and identified by the Surveillance, Epidemiology, and End Results (SEER) Cancer Registries of the greater metropolitan areas of Detroit and Los Angeles during a 14-month period from December 2001 to January 2003 were eligible for the study.

Database and Sampling

Staff members from both registries identified the study sample and implemented the mailing of the survey instrument using the same protocol. Eligibility criteria included the following: age 79 years or younger; a primary diagnosis of DCIS; no prior breast cancer diagnosis; had a definitive surgical procedure; resided in the catchment area of the SEER site; and could complete the questionnaire in English or Spanish. All Asian women diagnosed in Los Angeles

during the study period were excluded because these women were already being enrolled onto other studies.

We included all patients with DCIS (N = 1,108) in the preliminary study sample. Eighty-three patients were ineligible because they were too ill or had died (30 patients), were nonresidents (four patients), did not have surgery at time of contact (20 patients), had a prior cancer or no cancer (nine patients), or did not speak English or Spanish (20 patients). The survey was completed by 79.7% of eligible patients (n = 817). Compared with respondents, nonrespondents were of similar age but were less likely to be white (82.3% *v* 71.2%, respectively; $P < .001$) and more likely to have received a mastectomy (26.5% *v* 28.9%, respectively; $P = .002$). We excluded 158 patients (19.3%) from the analyses because subsequent SEER summary stage information confirmed that they had invasive disease (n = 149) or because stage information was missing (n = 9). Thus, the 659 patients who had DCIS by both preliminary pathology reports and final SEER summary stage were the sample used in this study.

Data Collection and Management

After physicians were notified of our intent to contact patients, an introductory letter was sent to all potential subjects followed by a telephone call to assess eligibility. A questionnaire and 10 dollar food coupon were mailed to all eligible women who agreed to participate and to women who could not be reached by phone. Patients were initially contacted approximately 3 months after diagnosis, and questionnaires were sent on a monthly basis. The average time from treatment to completion of the questionnaire was 7 months (range, 1 to 14 months). We used the Dillman survey method to encourage response.[26,27] The study protocol was approved by the Institutional Review Boards of the University of Michigan, Wayne State University, and the University of Southern California.

SEER staff stripped returned surveys of a cover sheet with identifying information, attached a unique patient identifier to each survey, and gave the surveys to University of Michigan staff. SEER-based data were merged with the survey data. Data entry and analysis of all survey data were performed at the University of Michigan.

Measures

The dependent variables were measures of surgical treatment and adjuvant radiation therapy. Surgical treatment received (mastectomy *v* BCS) was ascertained by self-report and the SEER data. Self-reports of mastectomy have been shown to be virtually 100% correlated with medical record data.[25] We found that self-report and SEER data yielded the same surgical procedure for 96.3% of patients in our sample. We used self-report of surgical treatment in all patients, except where self-report was ambiguous or missing (n = 5), in which case we used SEER data. Excluding patients for whom self-report and SEER data conflicted (n = 14) did not change the results in this study. The second dependent variable (initiation of radiation therapy) was ascertained by patient self-report or, if missing (n = 7), SEER clinical data.

The independent variables of interest included a measure of disease recurrence risk before surgery. A recurrence risk score was derived using three categories (lowest, intermediate, and highest risk). Women were coded into these categories using the two SEER variables of tumor size and histologic grade. We chose these variables because they are generally available to surgeons and patients before the surgical decision (through pathology and imaging data) and have been shown to be important predictors of clinical outcomes. Data from randomized trials,[11,13] population-based cohorts,[14] and large single-institution experiences[10] support the use of histologic grade as a predictor of the risk of recurrence after BCS for DCIS and as an indicator of greater benefit from radiotherapy.[11] Tumor size has also been shown to be a predictor of

recurrence in DCIS.[10–12] In addition, the amount of breast tissue that must be resected is an important predictor of cosmetic outcome. Although these variables are uniformly coded by SEER registry abstractors, one or both may be missing because of incomplete description in the medical record. Thirty-two patients (4.9%) were excluded from the analysis because they were missing both tumor size and histology information. However, we included the 171 patients (25.9%) who were missing either tumor size or histology information. Women were designated in the lowest risk category if they had well-differentiated tumors of 2 cm or less or had intermediate-grade tumors of less than 1 cm in size. Women were designated in the highest risk category if they had tumors greater than 2 cm with any histologic grade (including unknown grade) or had poorly differentiated tumors with unknown size. All other women were categorized as having intermediate risk.

Additional clinical variables included a count of medical comorbidities based on a list of six chronic conditions selected from the 2001 National Health Interview Survey.[28] Clinical contraindications to BCS or mastectomy were determined by evaluating patient reports of the reasons their surgeon gave them for recommending one procedure over the other. Women were asked whether they received a recommendation for one procedure or the other and what reasons were given for the recommendation (open ended). Two clinicians (S.J.K. and M.M) evaluated the responses and coded clinical contraindications to BCS if the reasons included any of the following: large tumor and small breast; diffuse or multifocal disease; inability to obtain clear margins after lumpectomy; or contraindication to radiation. Agreement between the two clinician observers was high ($\kappa = .85$).

We asked several questions pertaining to communication between patients and their surgeons with regard to local therapy. Patients were asked whether their surgeon described both BCS and mastectomy. Response categories were yes, no (he/she only described BCS), no (he/she only described mastectomy), and don't remember. We asked two additional questions about whether the women's surgeons or any other healthcare provider explained radiation therapy to them or recommended that they receive radiation therapy.

Patient concerns that influenced their decision about surgical options were ascertained by asking women who perceived choice the following question, which was followed by 23 items: "When you were deciding between mastectomy and lumpectomy, how much was your decision influenced by whether the treatment you chose. . . ." From these items, we conducted factor analyses and subsequently constructed a number of scales, two of which are used in this analysis and are as follows: concern about recurrence risk (four items, $\alpha = .85$); and concern about radiation (three items, $\alpha = .95$). Summary scores were interval measures that ranged from 1 (not influenced by attitude factor) to 4 (greatly influenced by the attitude factor). We collapsed each score into the following three categories: not influenced or slightly influenced (scores from 1 to 2.3), moderately influenced (scores from 2.4 to 3.3), and greatly influenced (scores from 3.4 to 4.0). Other independent variables included age (continuous), race (white, African-American, or other), education (less than high school, high school graduate, some college, or college graduate), and marital status (currently married or with partner *v* not married or with partner).

Analyses

We used logistic regression to calculate the proportion of patients who received mastectomy by recurrence risk level adjusted for age, race, education, marital status, medical comorbidity, and SEER site. We tested for differences in adjusted proportions between groups with Wald tests. We then performed bivariate analyses to examine whether patient reports of discussions with their surgeons about surgery treatment options varied across risk groups. Finally, we used logistic regression to calculate proportions of patients who received mastectomy for groups defined by level of concerns regarding both disease recurrence and radiation side effects using

one model that simultaneously controlled for age, education, marital status, race, medical comorbidity, recurrence risk, and SEER site.

We took a similar approach to evaluating correlates of radiation therapy for women who received BCS. First, we calculated the proportion of patients who received radiation after BCS by recurrence risk and SEER site adjusted for age, education, race, and medical comorbidity. We then performed bivariate analyses to evaluate whether patient reports of discussions with their surgeons about radiation therapy after BCS varied by recurrence risk group. We then examined whether patient concerns about radiation side effects were associated with receipt of radiation. All analyses were evaluated for second-order interactions between selected covariates. We also adjusted point estimates for design effects by weighting the data using a sample weight that accounted for differential selection by race and nonresponse.

Sensitivity analyses were performed to evaluate potential sources of bias. We found consistent results when we accounted for incomplete or missing clinical data in the regression models of receipt of treatment. Accounting for the time between the diagnosis date and questionnaire completion date did not change the findings described in this study. Finally, alternative approaches to modeling correlates of treatment use (eg, multinomial logistic regression using a dependent variable indicating receipt of mastectomy, receipt of BCS with radiation, and receipt of BCS without radiation *v* the main analyses using a two-part approach) yielded similar results.

RESULTS

Sample Characteristics

Table 1 lists the weighted percent distribution of the characteristics of the patient sample. The mean age was 58.8 years; 67.6% of patients were white, 19.0% were African-American, and 10.7% were other race. More than half of the respondents had some college experience or were college graduates, and more than half were living with a spouse or partner; 37.4%, 26.2%, and 28.4% of patients had no, one, or two or more medical comorbid conditions, respectively. Approximately one fifth of respondents were in the lowest recurrence risk group, whereas about one quarter of respondents were in the highest recurrence risk category. Mastectomy was performed in 30.5% of patients, and 70.8% of women who underwent BCS received radiation.

Receipt of Mastectomy by Recurrence Risk Group

Figure 1 shows the percentage of women who received a mastectomy by level of recurrence risk. Only 14.0% of patients at lowest risk received a mastectomy compared with 22.8% and 52.6% of patients in the intermediate and highest risk groups, respectively ($P < .001$). Age was also independently associated with surgical treatment because younger women were more likely than older women to receive mastectomy (odds ratios = 0.77, 0.49, and 0.28 for age groups 50 to 59, 60 to 69, 70 to 79 years, respectively, *v* women under age 50 years; Wald test, 15.5; $P = .001$). There was no significant difference in the use of mastectomy between the two SEER sites (adjusted odds ratio = 1.2; 95% CI, 0.8 to 1.8).

Patient-Provider Communication by Recurrence Risk Group

The pattern of surgical treatment observed across risk groups was consistent with patients' descriptions of discussions with and recommendations made by their surgeons (Fig 2). Overall, 69.0% of patients reported that their surgeon(s) discussed both mastectomy and BCS, 26.7% reported that their surgeon(s) only described BCS, and 4.3% reported that their surgeon(s) only described mastectomy. These figures varied by patient recurrence risk group. Compared with the lowest risk group, the highest risk patients reported more discussion of both options, less discussion of BCS alone, and somewhat more discussion of mastectomy alone. However, even

in the highest risk group, only 9.4% of patients reported that mastectomy was discussed as the only treatment option, and most of these patients (56.8%) reported a contraindication to BCS. A similar pattern was observed for surgeon recommendation (Fig 2). Overall, 31.9% of patients reported that their surgeon(s) did not recommend one procedure over the other, 52.8% reported that their surgeon recommended BCS, and 15.3% reported that their surgeon recommended mastectomy. Compared with women in the lowest recurrence risk group, women in the highest risk group were less likely to report that their surgeon recommended BCS and more likely to report that their surgeon recommended mastectomy. However, 40.9% of women in the highest risk group received a recommendation for BCS, whereas only 26.9% were advised to undergo mastectomy, most of whom (58.4%) reported a contraindication to BCS. Most women received the surgical treatment option recommended by their surgeon (88.3% and 88.6% of women who reported a recommendation for BCS and mastectomy, respectively).

Figure 3 shows that patient concerns about recurrence risk and radiation side effects were also powerful independent correlates of receipt of mastectomy. Only 13.1% of patients who were not influenced or were slightly influenced by concerns about recurrence received mastectomy compared with 48.8% of women who were greatly influenced by this concern ($P < .001$). Similarly, only 16.0% of women who were not influenced or were slightly influenced by a concern about radiation received mastectomy compared with 70.2% of women who were greatly influenced by this concern.

Receipt of Radiation After BCS by Recurrence Risk Group

Figure 4 shows the receipt of radiation after BCS by recurrence risk and SEER site. Overall, a lower proportion of patients in Los Angeles than in Detroit received radiation (61.4% *v* 79.2%, respectively; $P < .001$). Between-site differences were greater for lowest risk women (38.9% in Los Angeles *v* 70.5% in Detroit) versus highest risk women (80.2% in Los Angeles *v* 85.9% in Detroit). Interactions between recurrence risk and site were significant (Wald test, 12.4; $P = .006$).

Between-site differences in use of radiation after BCS were consistent with patient recall of surgeon discussion and recommendations, as shown in Figure 5. Between-site differences for surgeon recommendation of radiation therapy were greatest for women with the lowest recurrence risk. The proportion of women in the lowest recurrence risk group who reported a surgeon recommendation for radiation therapy was 59.1% in Los Angeles compared with 81.5% in Detroit, whereas these figures were 90.5% and 89.0% for highest recurrence risk women in Los Angeles and Detroit, respectively (Wald test for the interaction between risk group and site, 6.0; $P = .051$). Patients who were greatly influenced by concerns about radiation effects (7.8%) were much less likely to receive radiation after BCS than other women (22.3% *v* 87.6%, respectively; Wald test, 19.5; $P < .001$).

DISCUSSION

We performed a population-based study of the correlates of surgical treatment and adjuvant radiation therapy for women diagnosed with DCIS in 2002 in the metropolitan areas of Los Angeles and Detroit. We found that the receipt of different surgical treatment options was highly associated with recurrence risk when tumor size and histologic grade were used as measures of the risk of recurrence. Nearly nine out of 10 patients in the lowest risk group received BCS, whereas less than half of the patients in the highest risk group received BCS. Surgeon discussion and recommendation seemed to be powerful factors contributing to this practice pattern. Two thirds of patients received a recommendation from their surgeons. Compared with patients in the highest recurrence risk group, patients in the lowest recurrence risk group were more likely to have discussed only BCS with their surgeons and were much more likely to have received a recommendation for BCS. A substantial proportion of women

who received a recommendation for mastectomy recalled a clinical contraindication to BCS based on conservative coding criteria. Most women received the surgical treatment recommended by their surgeon(s).

However, patients' attitudes also were powerful contributing factors to receipt of surgical treatment. Many patients reported that their decision about surgery was greatly influenced by concerns about recurrence of disease and, to a lesser extent, concerns about the side effects of radiation. These patients were much more likely to have received mastectomy compared with patients who reported being less influenced by these concerns. These patient attitudes seemed to explain the large difference between the proportion of women who underwent mastectomy and the proportion of women who reported that their surgeon recommended a mastectomy. For example, more than half of patients in the highest risk group underwent mastectomy, but only approximately one quarter of patients in this group reported that their surgeon recommended a mastectomy. Taken together, surgeon clinical recommendations and patient preferences strongly drove the decision to perform mastectomy; eight of 10 women who had high-risk tumors and were greatly concerned about disease recurrence received mastectomy, whereas only one of 25 women at low risk whose decision was not influenced or was only slightly influenced by recurrence concerns received mastectomy.

Use of radiation therapy after BCS also varied markedly by recurrence risk group. Women with the lowest risk of recurrence were less likely to have received radiation after BCS than women at highest risk. But this was much more the case in Los Angeles than in Detroit. These regional differences seemed to be explained by regional differences in surgeons' recommendations for radiation after BCS. Patient attitudes also played a role in the receipt of radiation after BCS. Patients who reported being greatly concerned about the side effects of radiation were less likely to have received radiation after BCS. Together, patient attitudes and surgeon attitudes strongly limited the use of radiation after BCS in low-risk women. For example, in Los Angeles, nine of 10 women at highest risk and who were not concerned or only slightly concerned about radiation side effects received radiation after BCS, whereas two of 10 women at lowest risk whose decision was moderately or greatly influenced by concerns about radiation side effects received radiation. These patient and surgeon perspectives seem to reflect legitimate individual variation in attitudes towards risks and benefits of treatment and cannot be deemed inappropriate.

Several aspects of the study merit comment. Although our study was population-based, we had to exclude Asian women with DCIS in Los Angeles because of their involvement in other studies. Thus, our findings cannot be generalized to this group. The recurrence risk measure we derived was based on tumor size and histologic grade. Other factors, such as patient age and margin status,[11–13,18] are predictors of outcomes and may be important factors in surgical treatment decisions. Our risk analyses for both receipt of mastectomy and radiotherapy were adjusted for age. However, pathology data describing margin status was not available. The majority of DCIS presents as mammographic abnormalities, and core needle biopsy is the most common method of diagnosis.[29,30] Thus, at the time of initial surgical decision making, margin status is often unknown or may be of limited importance in initial treatment choice. However, after attempts at definitive surgical treatment, margin status assumes much greater importance in decision making because patients with persistent positive margins are at high risk for local recurrence and should undergo mastectomy.[15] Although the risk measure we used provides a reasonable approximation of risk status based on what is generally known at an initial surgical consultation, the addition of information about margin status might improve the accuracy of the risk measure. Because persistent positive margins are correlated with tumor size and subsequent receipt of mastectomy, incorporating margin status into the recurrence risk measure would likely strengthen the association between measure and surgeon recommendation for mastectomy that we found in our study. We could have underestimated

clinical contraindications to BCS because our coding criteria were conservative and patient reports based on one open-ended question may have been imprecise. The study was necessarily retrospective in design. Patients' recall of their encounters with clinicians may vary because of the passage of time or be influenced by their posttreatment experiences.

Our results have important implications for patients, providers, and policy. Some investigators and policy groups have argued that persistently high rates of mastectomy for women with noninvasive breast cancer suggest overtreatment,[2,6,8,15,17,19,20,31] whereas the failure of women to receive radiation after BCS is considered by some to be undertreatment.[2,25,32] However, our findings should temper these concerns because they suggest that surgeon recommendation for mastectomy is infrequent, highly associated with patient report of clinical contraindications to BCS, and highly associated with known clinical indicators of local recurrence risk. Differences between surgeon perspectives in Los Angeles and Detroit regarding radiation after BCS seem to be the result of legitimate differences in the perspectives of regional opinion leaders regarding this issue, especially for patients at low attributable risk of recurrence.[17,21]

The powerful role patient attitudes and preferences play in treatment decision making underscores the need for clinicians to communicate clearly about risks and benefits of treatment. Prognosis for patients with DCIS is excellent across several treatment options. Yet, a substantial proportion of patients with DCIS do not accurately recall basic information about risks and benefits of treatment (Fagerlin et al, submitted for publication).[33] Thus, it is particularly important to discuss survival and local recurrence risk issues with patients. Improving the precision of clinical recurrence risk assessment for women with DCIS may help facilitate these discussions and ultimately improve the match between patient preferences and appropriate receipt of local therapy.

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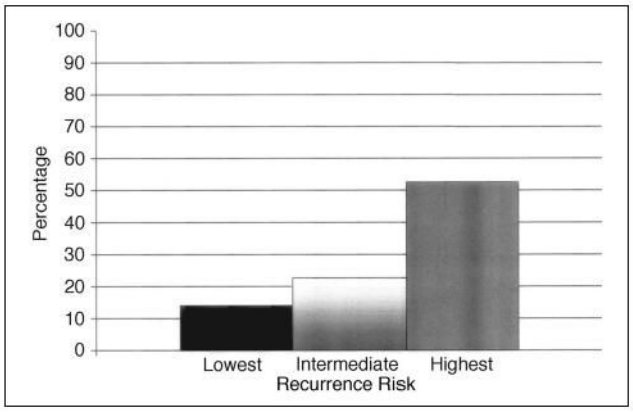

Fig 1.

Receipt of mastectomy by risk of recurrence. Mastectomy rates are adjusted for age, education, race, marital status, medical comorbidity, and Surveillance, Epidemiology, and End Results Registry site (n = 627; Wald test, 53.0; $P < .001$).

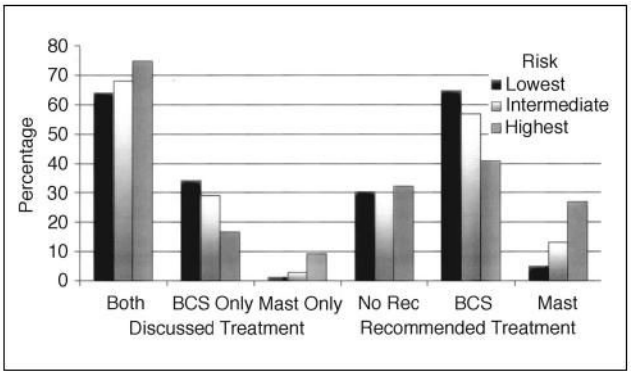

Fig 2.

Surgeon discussion and recommendation of surgical treatment options by risk of recurrence. Wald test for interaction between recurrence risk group and site was 20.2 ($P < .001$) for discussion and 30.5 ($P < .001$) for recommendation (n = 627). BCS, breast-conserving surgery; Mast, mastectomy.

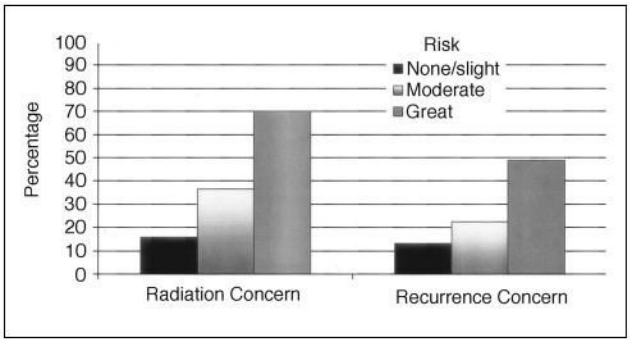

Fig 3.

Receipt of mastectomy by level of patient concern and risk of recurrence. For women who perceived a choice between surgical treatments (n = 409), proportions were adjusted for age, education, race, marital status, medical comorbidity, recurrence risk, and Surveillance, Epidemiology, and End Results Registry site (Wald test, 23.0; $P < .001$ for radiation concern; and Wald test, 39.9; $P < .001$ for recurrence concern).

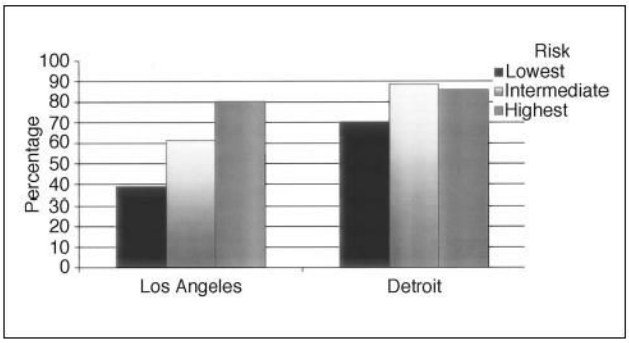

Fig 4.

Receipt of radiation after breast-conserving surgery by recurrence risk and Surveillance, Epidemiology, and End Results Registry site. Proportions adjusted for age, education, race, and medical comorbidity (n = 442; Wald test for interaction between recurrence risk group and site, 12.4; *P* = .006).

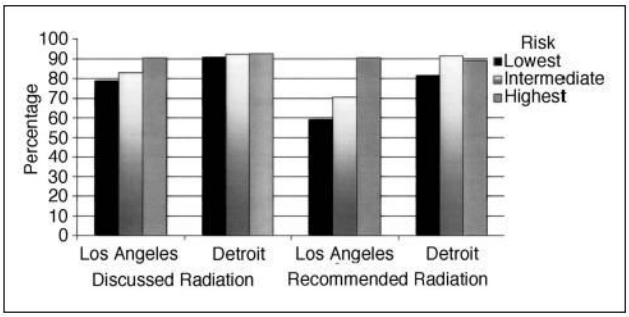

Fig 5.

Surgeon communication regarding radiation after breast-conserving surgery by risk of recurrence and Surveillance, Epidemiology, and End Results Registry site (Wald test for interaction between recurrence risk group and site, 6.0; $P = .051$; n = 442).

Table 1

Study Sample Characteristics

Variable	Unweighted No. of Patients (N = 659)	Weighted %
Mean age, years	58.8	
Race		
White	446	67.6
Black	117	19.0
Other	80	10.7
Missing	16	2.7
Education		
College graduate and higher	182	26.8
Some college	221	33.2
High school graduate	123	19.0
< High school	77	11.6
Missing	56	9.4
Marital status		
Married or partnered	367	55.4
Not currently married or partnered	232	35.3
Missing	60	9.3
Medical comorbidities		
0	255	37.4
1	173	26.2
2 or more	181	28.4
Missing	50	8.0
Recurrence risk		
Lowest	140	21.9
Intermediate	318	46.6
Highest	169	24.7
Missing	32	5.3
Surgery type		
BCS	459	69.5
Mastectomy	200	30.5
Radiation after BCS		
Yes	318	70.8
No	141	29.2

Abbreviation: BCS, breast-conserving surgery.