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13. ABSTRACT *(Maximum 200*

The goal of this project is to study the relationship of initial surgical treatment for breast cancer to specific outcomes. We have completed substantial work on the development of an algorithm to use Medicare data to identify women undergoing treatment for breast cancer. The specificity of the algorithm is 99.95% when using hospital claims, but 99.3% when using hospital and physician claims.

By studying tumor registry patients in nine locations across the United States, we have determined that the rate of receipt of appropriate initial breast care (defined as total mastectomy plus lymph node dissection, or breast-conserving surgery with radiotherapy and lymph node dissection) has decreased by about 10% from 88% in 1990 to 78% by the end of 1995.

This decrease in the percentage receiving appropriate therapy occurred in all age groups. It was more prominent among those residing in more urban areas, and appears attributable mostly to women undergoing breast-conserving surgery without radiotherapy or without lymph node dissection.

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5.) INTRODUCTION

Almost half of the incident cases of breast cancer occur in women aged 65 and older. However, patients in this age group are infrequently enrolled into randomized clinical trials and have been seriously under-represented in the randomized trials of breast-conserving surgery (BCS) vs mastectomy. The randomized trials of younger women suggest that receipt of BCS without radiotherapy is associated with an increased risk of local disease recurrence, but no definite decrease in overall survival.

The goal of this study is to study outcomes associated with different breast cancer treatments in a population-based observational cohort of women aged 65 and older who have undergone surgical treatment for early stage breast cancer. The specific aims are:

1. To develop algorithms to utilize Medicare inpatient and outpatient data to define and study the treatments received and outcomes associated with the use of BCS with or without radiotherapy and mastectomy among older women with early stage breast cancer.

2. To determine predictors of receipt of radiotherapy among older women with early stage breast cancer who have undergone BCS.

3. To determine specific outcomes, especially treatment for local/regional disease recurrence, associated with receipt of BCS with radiotherapy, BCS without radiotherapy, and mastectomy among older women with early stage breast cancer.

To accomplish these aims we proposed methods for using the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) tumor registry data and Medicare claims files.

6.) BODY

Work has progressed nicely since the previous report. We summarize below the specific aims.

Specific Aims #1: Develop Algorithms Using Medicare Data.

Methods

Previously we had selected a cohort of women in the SEER cohort who were aged 65-79 years at the time of diagnosis in 1992 of a local or regional stage breast cancer. Women who had not undergone either mastectomy or BCS therapy for the breast cancer were excluded. Additional subjects were excluded if they did not have Medicare parts A & B coverage for all of 1992, or were enrolled in a Medicare HMO for any month during 1992.

For each subject in the breast cancer cohort, a control patient was then selected. The control patients were selected from a 5% random sample of Medicare beneficiaries residing in the same counties covered by the SEER tumor registry program. The 5% random sample had previously been purged of subjects who are found in the SEER data base, and thus represent controls who do not have any type of cancer. For each breast cancer cohort subject, a cancer-free control was chosen, matched for gender, age (within 1 year) and matched for SEER geographic site (Atlanta, Detroit, Connecticut, etc). This cohort of 5391 subjects is referred to as the cancer-free cohort.

The algorithm we had previously developed (Refs. 1, 2) for selecting patients undergoing a primary breast cancer operation was applied to the breast cancer cohort, to determine the sensitivity and proportion of true positive within that population. The same algorithm was then applied to the cancer-free control cohort to determine the proportion of false positives, to permit estimation of the overall population positive predictive value of the algorithm. In each case the algorithm was applied initially only to Medpar (inpatient hospital) claims. The algorithm was then applied to a combination of Medpar, part B (physician bills) and standard analytic file (SAF) (outpatient facility) claims.

Results

The results of the algorithm in detecting breast cancer cohort patients who mastectomy or BCS are presented in Table 1. The sensitivity is higher for detecting mastectomy patients than for BCS patients, and is higher when outpatient SAF and part B claims are included.

The results for discriminating stage of disease are shown in Table 2. The sensitivity for detecting local breast cancer based on the diagnostic codes is higher with the Medpar, part B, and SAF combination than with Medpar alone. However, the sensitivity for detecting regional disease is modest, regardless of the claims used.

Table 1. Sensitivity of Naive Algorithm using Medicare claims to determine breast cancer treatment undergone, among a cohort 4391 SEER subjects who were diagnosed with breast cancer in 1992

Treatment	Claims Used	Sensitivity	PPV*
Mastectomy	Medpar	0.873	0.973
Mastectomy	Medpar, B, SAF	0.886	0.973
BCS	Medpar	0.445	0.936
BCS	Mepar, B, SAF	0.764	0.916

*PPV = proportion of positive claims that were true positives, and is only applicable to women having breast cancer according to SEER.

Table 2. Sensitivity of the Naive Algorithm using Medicare claims to determine breast cancer diagnosis and stage, among a cohort of 4391 SEER subjects who were diagnosed with breast cancer in 1992.

Stage	Claims Used	Sensitivity	PPV*
Local	Medpar	0.687	0.907
Local	Medpar, B, SAF	0.821	0.913
Regional	Medpar	0.616	0.965
Regional	Medpar, B, SAF	0.598	0.960

*PPV = proportion of positive claims that were true positives, and is only applicable to women having breast cancer according to SEER.

Table 3. False positive rates for the Naive Algorithm using Medicare claims to determine breast cancer treatment or diagnosis, when applied to 4391 cancer-free control patients.

	Medpar Alone	Part B Alone	Medpar and Part B
Breast Cancer Treatment	5 (0.1%)	55 (1.3%)	55 (1.3%)
Breast Cancer Diagnosis	2 (0.05%)	31 (0.7%)	31 (0.7%)

NB: Each subject who was a false positive based on Medpar also had a false positive part B claim.

The false positive rates when applying the algorithm tot he cancer-free controls are presented in Table 3. WE found that the SAF outpatient files did not have incremental value over the Medpar and part B files, so show results only for these. Using Medpar files provides excellent specificity, at a level that we had determined previously would be necessary to maintain.

A positive predictive value of at least 80% (see last years' annual report, p 16). Using the part B files introduces a false positive rate that is small, but substantially higher than with the Medpar claims alone. The false positive rate for treatment codes is particularly low. On inspection of the claims, it appears that some of these false positives may represent breast cancer cases not included in the SEER registry (based on consistency of billing codes by surgeon, anesthesiologist, and hospital). Although the SEER registries have high quality data collection procedures, a few cancer cases are probably missed. Nonetheless, we plan to analyze this data using a record in SEER as the gold standard for defining breast cancer.

Tasks 1-4 for this specific aim have been accomplished. The last task to be accomplished for this specific aim is to determine whether the algorithm can be optimized. We will be using a recursive partitioning technique (CART) to attempt to optimize the specificity of the algorithm when applied to Medpar and part B data while maintaining the algorithm sensitivity. Completion of this task has been delayed by Dr. Craig Beam's move to Northwestern University's Cancer Center. However, Dr. Beam has agreed to finish the algorithm development project with us, and this phase should be completed soon.

Specific Aims #2. Determine Predictors of Receipt of Radiotherapy.

Since the algorithm for using Medicare claims was not yet completed, we elected to begin work on this specific aim using the SEER data. Since writing the grant, we have become aware that not only do some women not undergo radiotherapy after BCS, some women do not undergo axillary lymph node dissection, in apparent conflict with the National Cancer Institute Consensus Guidelines (Ref. 3). Therefore, we have studied the use of appropriate primary therapy, as articulated by the 1990 NIH Consensus conference on early stage breast cancer.

Methods

We used the NCI's Seer registry as the source of data on breast cancer patients and their care. We initially selected 147,432 women who were aged 30 or older at the time of first diagnosis of a local or regional stage unilateral breast cancer between 1983 and 1995. We have utilized similar methods previously. (Refs. 4, 5) We excluded 1887 (1.3%) women who did not undergo primary therapy with BCS or mastectomy, or whose type of surgery was unknown. We excluded 55 women (0.04%) whose date of diagnosis was unknown. This left a study cohort of 145,490 women.

Based upon the June, 1990 NIH Consensus Development Conference (Ref. 3), the minimum requirements for appropriate primary therapy were determined to be total mastectomy with lymph node dissection or BCS with lymph node dissection and radiotherapy. Women who underwent subcutaneous mastectomy, total mastectomy without lymph node dissection, BCS without radiotherapy, or BCS without lymph node dissection were categorized as not meeting the consensus standard. For 731 (0.5 %) of the 145,490 women, we could not determine whether care met the standard, because it was unknown whether they had undergone radiotherapy.

The time period from 1983 through 1995 was broken into 3 month periods. The patients were categorized into these periods based on month and year of diagnosis. For each time period, the percentage of women who received appropriate therapy (according to the definition above) was calculated.

A multivariate logistic model was constructed to permit adjustment of proportion appropriate for the fact that patients treated during each quarter might differ according to age, stage of disease, race, or size of MSA. The model also permitted a more precise assessment of trends in appropriateness of care over time, and calculation of adjusted odds ratios for receipt of appropriate care. In constructing the model, a logistic spline was used. Knots were permitted at the beginning of each year, and also semi-annually from 1989-1991 (around the time of the consensus conference). A forward stepwise regression analysis was used to include only those knots that were statistically significant. In addition, the covariates of age, race, stage, and size of MSA, and stage were included in the models when indicated.

Results

The characteristics of the study cohort are presented in Table 1. About two-thirds of the patients had local stage disease. Most were white and most resided in urban areas. There were increasing numbers of breast cancer patients over time. Overall, about one-third of the patients underwent BCS; the remainder had mastectomy treatment. Consistent with previous reports, (Refs. 4, 5) the use of BCS rose from 1983 to 1985, was relatively stable through mid-1990, then rose steadily through 1995 (Fig.1).

The percentage of women receiving appropriate primary therapy was about 88% from 1983 to approximately 1989 (Figure 1), then decreased to a low of about 78% at the end of 1995. The multivariate model, which adjusted for age, race, stage, and size of MSA, confirmed a constant level of appropriateness from 1983-88, a small drop in the first half of 1989, a small increase in the second half of 1989, and a consistent decrease from the second half of 1990 through 1995.

As has been reported previously, the percentage receiving appropriate therapy was lower in women aged 65-79 years than in younger women, and was much lower in women aged 80 and older (Fig. 2). The multivariate model showed the rate of decrease in appropriateness over time to be greatest among women aged 64 and younger, with a smaller rate of decline over time among women aged 65-79 years, and the least decline among women aged 80 and older. Compared to white women, women with local stage disease were consistently less likely to receive appropriate therapy than those with regional stage disease across this time period (Fig. 3). However, the multivariate model showed no difference by stage in the rate of decline during the 1990's. Women residing in more urban areas were slightly less likely to receive appropriate therapy during the 1980's, and during the 1990's the rate of decline in appropriateness was greater among more urban residents. By the end of 1995, about 76% of women residing in MSA's of 250,000 persons or more received appropriate care, compared to 85% of those residing in more rural areas (Fig. 4).

Components of Care Not Meeting the Consensus Standard

Since the decrease in percentage of women receiving appropriate care coincided temporally with a substantial increase in use of BCS, we hypothesized that the decrease in percentage of patients receiving appropriate therapy might be associated with greater use of BCS. Figure 5 shows the percentage of women receiving care not meeting the consensus standard, by type of treatment undergone. The percent of patients receiving mastectomy treatment not meeting the standard (total mastectomy without lymph node dissection or subcutaneous mastectomy) remained stable at about 2.7% throughout most of the study period. In contrast, the percentage undergoing BCS treatment not meeting the standard (no radiotherapy and/or no lymph node dissection) rose from about 10% in 1989 to almost 19% at the end of 1995. The women undergoing BCS whose care did not meet the standard were about equally likely to have radiotherapy omitted as they were to have lymph node dissection omitted.

Among those women undergoing BCS, the percentage who underwent radiotherapy and lymph node dissection rose during the mid-1980's and remained stable at about 65% during the 1990's (Fig. 6). Of the women who underwent BCS, roughly equal proportions underwent BCS without radiotherapy, BCS without lymph node dissection, and BCS without either radiotherapy or lymph node dissection by 1995. Therefore the decrease in percentage of patients in the entire cohort undergoing appropriate treatment was related to the overall increase in use of BCS, and was not attributable to a decrease in the percentage of the BCS patients who underwent radiotherapy and lymph node dissection (Fig. 6). While the annual number of women treated for breast cancer in this cohort increased 14% from 1989 to 1995 (from 11,031 patients in 1989 to 12,622 patients in 1995), the annual number of women receiving conservative treatment not meeting the consensus guideline nearly doubled over the same time period (from 1158 in 1989 to 2207 in 1995).

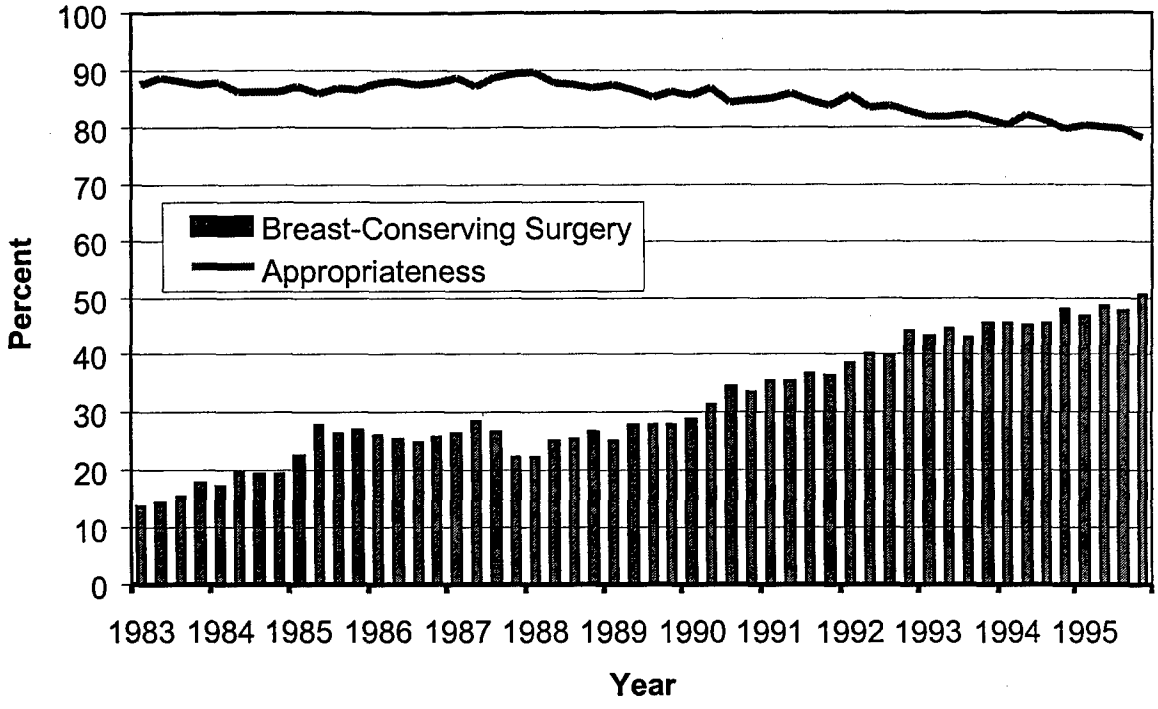

Figure 1.
Use of breast-conserving surgery and use of therapy considered appropriate by the 1990 National Cancer Institute Consensus Statement on early stage breast cancer, among 145,490 women from the Surveillance, Epidemiology, and End Results registry, who were diagnosed between 1983 and 1995.

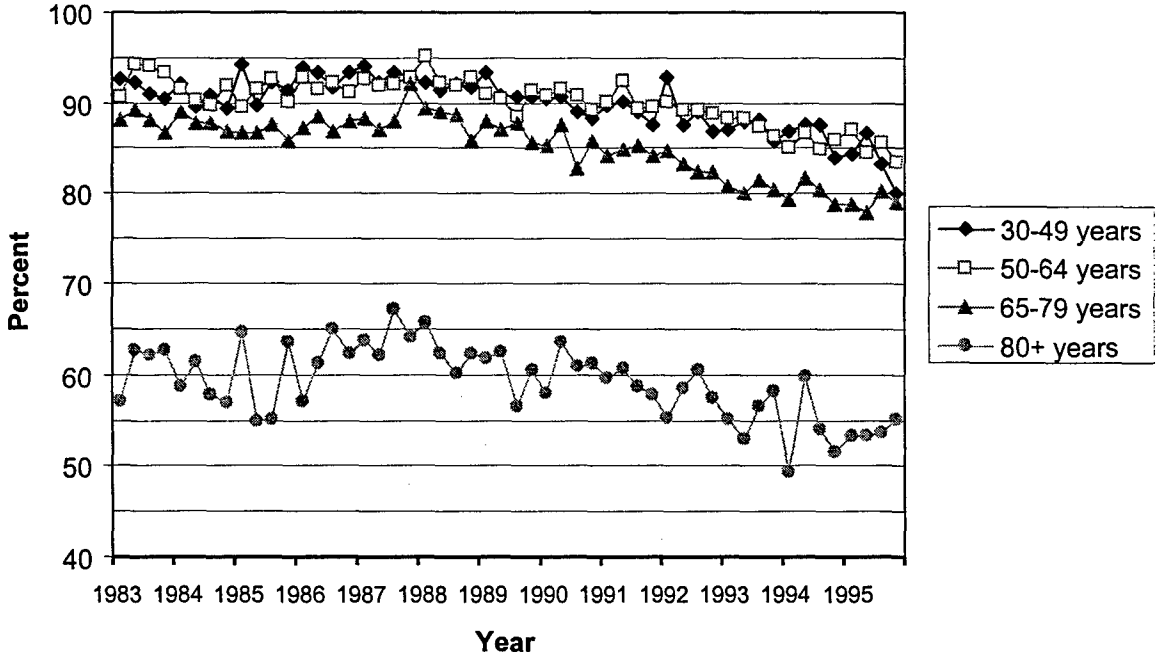

Figure 2.
Use of therapy considered appropriate by the 1990 National Cancer Institute Consensus Statement on early stage breast cancer, by patient age at diagnosis.

(Proprietary data)

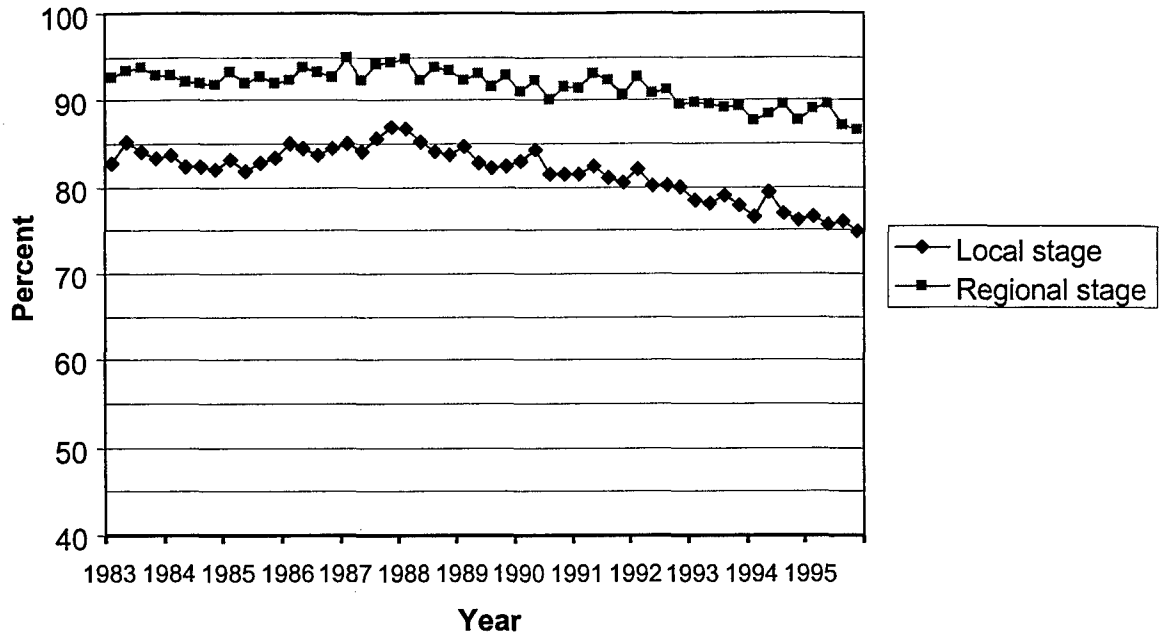

Figure 3.
Use of therapy considered appropriate by the 1990 National Cancer Institute Consensus Statement on early stage breast cancer, by stage at diagnosis.

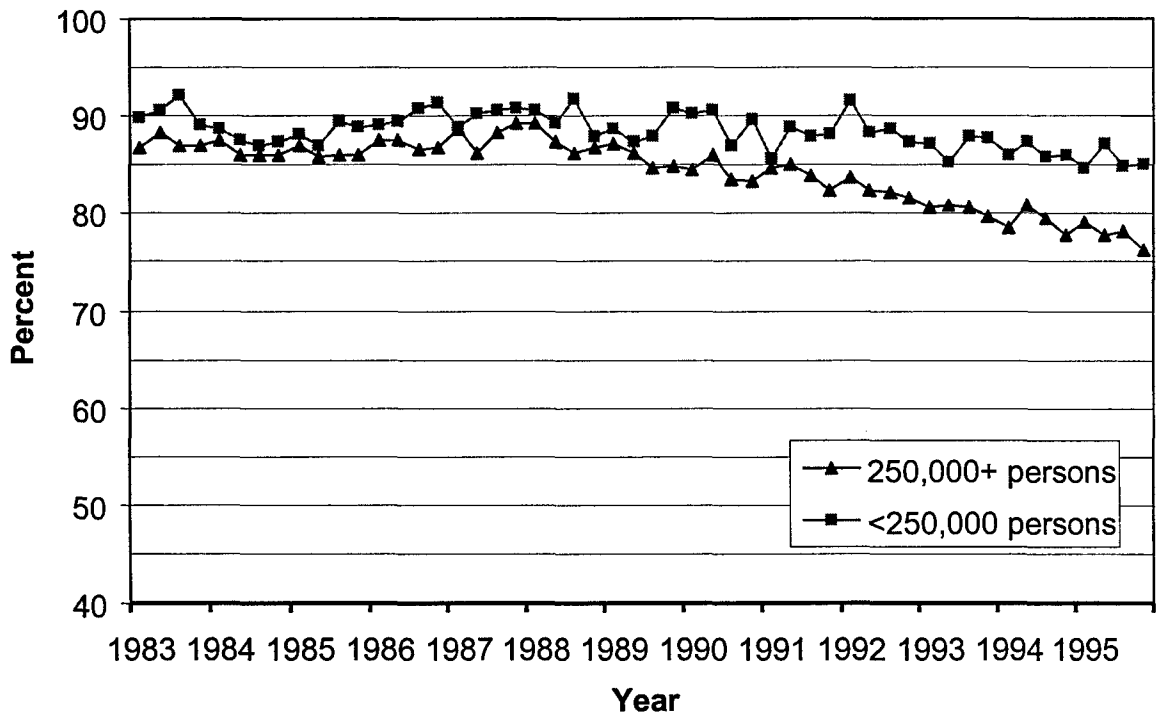

Figure 4.
Use of therapy considered appropriate by the 1990 National Cancer Institute Consensus Statement on early stage breast cancer, by size of the metropolitan statistical area.

(Proprietary data)

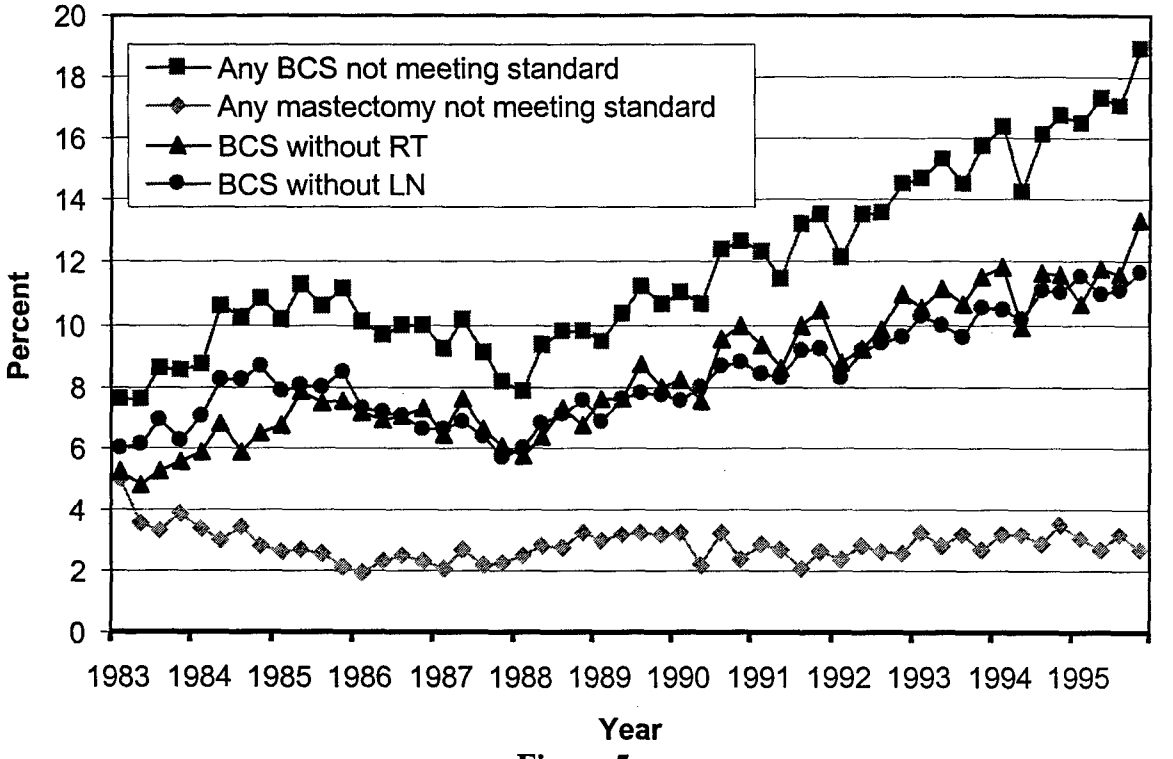

Figure 5.

Percentage of women undergoing care that did not meet the 1990 National Cancer Institute Consensus Statement standards, by type of treatment undergone. At each time point, the percentage undergoing breast-conserving surgery (BCS) without radiotherapy and the percentage undergoing BCS without axillary lymph node dissection add to more than the total undergoing any inappropriate BCS because some women underwent neither radiotherapy or axillary lymph node excision.

(Proprietary data)

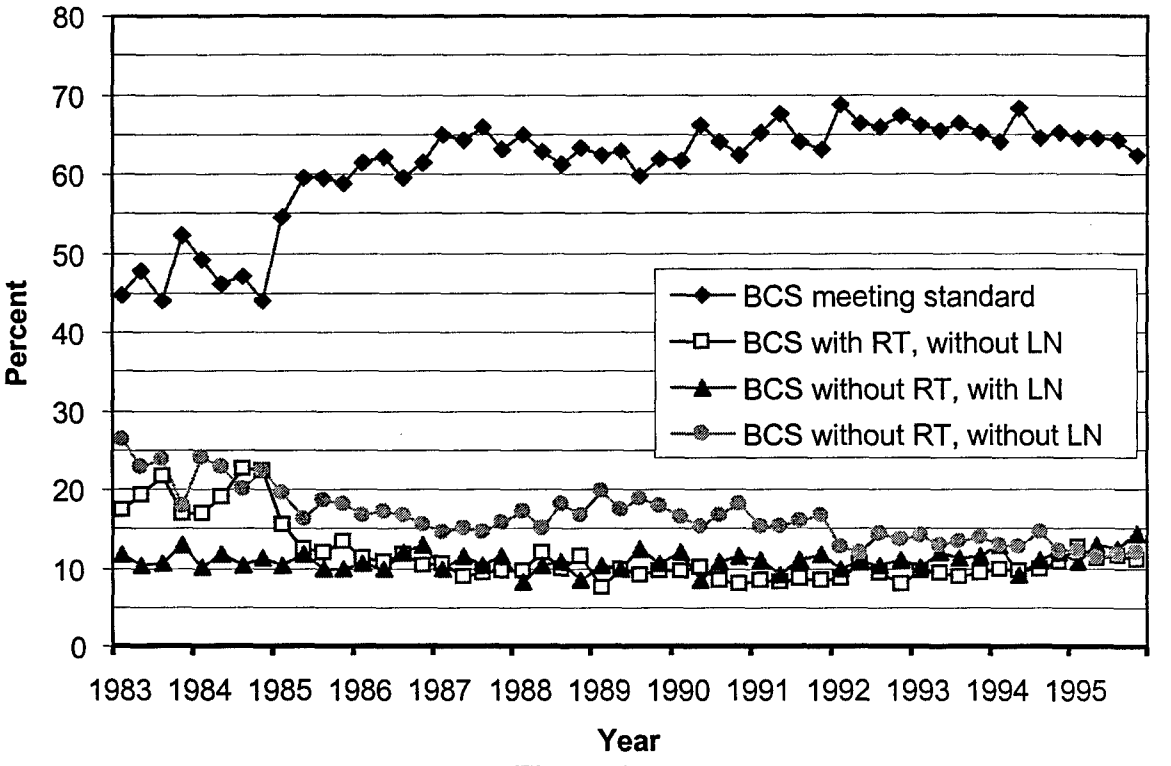

Figure 6.

Of women undergoing breast-conserving surgery, the percentage undergoing both radiotherapy and axillary lymph node dissection, or omitting either radiotherapy, axillary lymph node dissection or both.

(Proprietary data)

7.) CONCLUSIONS

We conclude that a naïve algorithm has modest sensitivity and high specificity for identifying breast cancer patients who have undergone surgical treatment. The use of Part B claims improves the algorithm sensitivity, but decreases the specificity.

We conclude that the appropriateness of initial primary therapy for women with early breast cancer decreased from 1990 to 1995, due to both omission of radiotherapy and omission of lymph node dissection with BCS. The use of appropriate primary therapy is lower among women aged 65 and older than among younger women, is lower among women with local stage disease than regional stage, and is lower among women residing in more urban areas.

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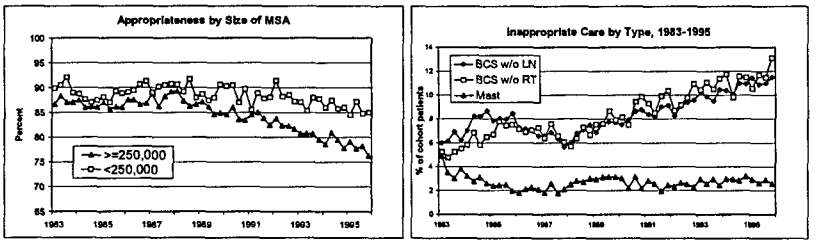
DECREASE IN APPROPRIATENESS OF BREAST CANCER CARE ASSOCIATED WITH INCREASED USE OF BREAST-CONSERVING SURGERY. AB Nattinger, RG Hoffmann, RT Kneusel, MM Schapira, Division of GIM, Department of Medicine, Medical College of Wisconsin, Milwaukee, WI.

Compared to mastectomy, breast-conserving surgery (BCS) is an appropriate, but more complex, therapy for early stage breast cancer, in that axillary lymph node dissection (through a separate incision) and postoperative radiotherapy are required. To determine whether the percent of women receiving appropriate care has remained stable as BCS has been adopted more widely into practice, we studied 145,490 women included in the national Surveillance, Epidemiology, and End Results (SEER) tumor registry who were aged 30 or more at the time of diagnosis of local or regional breast cancer between 1983 and 1995, and who underwent BCS or mastectomy treatment. The minimum requirements for appropriate primary therapy were considered to be total mastectomy with lymph node dissection or BCS with lymph node dissection and radiotherapy, and the percent receiving appropriate care was calculated for each calendar quarter. The rate of appropriate care remained at about 88% from 1983 until mid-1990, from which point it fell steadily to about 78% in 1995 ($p<0.001$). The decrease in rate of appropriate care was observed in women of all age groups, in white and non-white women, and in women with both local and regional stage disease. The decrease in appropriate care was more prominent in women residing in more urban areas, compared to women residing in more rural areas ($p<0.001$, Figure). Changing demographics over time did not account for the decrease in appropriateness.
Investigation of the type of inappropriate care revealed that the percent of women undergoing an inappropriate form of mastectomy was stable at about 3% over the period of observation, but the



percent undergoing inappropriate BCS therapy (ie, no radiotherapy or no lymph node dissection) rose from about 9% to almost 19% by 1995, concomitant with an increase in use of BCS rather than mastectomy (Figure). The type of inappropriate BCS therapy was about equally omission of radiation and omission of lymph node dissection. We conclude that the appropriateness of breast cancer primary therapy has decreased since 1990. The decrease is mostly attributable to BCS therapy which does not meet consensus standards for radiotherapy or lymph node dissection.

Abstract accepted for oral presentation at the national meeting of the Society for General Internal Medicine, April, 1999.

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