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CONTRACTING ORGANIZATION: Medical College of Wisconsin
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13. ABSTRACT *(Maximum 200*

The goal of this project is to develop from secondary data bases a population-based observational cohort to study the relationship of initial surgical treatment for breast cancer and specific outcomes. In the initial grant year, work has focused on the development of an algorithm to identify women with early stage breast cancer treated with mastectomy or breast-conserving treatment (BCT) using Medicare claims. Compared to Surveillance, Epidemiology and End Results (SEER) Registry data, in-patient Medicare data have been found to have 87% sensitivity for mastectomy cases but only 45% sensitivity for BCT cases. Addition of outpatient Medicare claims improves the sensitivity for BCT cases, but the specificity of the algorithm when applied to a general Medicare population requires further assessment. Due to the low incidence of breast cancer in the general Medicare population, a specificity of $\geq$ 99.9% may be required to attain a sufficiently high positive predictive value for the algorithm.

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5.) INTRODUCTION

About 45% of the incident cases of breast cancer in this country 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 vs mastectomy. The randomized trials of younger women suggest that receipt of breast-conserving therapy (BCT) without radiotherapy is associated with an increased risk of local disease recurrence, although no definite decrease in overall survival. It is not known whether this risk of local recurrence also applies to older women. Although there is no clear evidence that older women cannot tolerate breast irradiation, data from several geographically diverse sources have shown that fewer than 50% of women aged 65 and older who undergo BCT actually receive radiotherapy.

The goal of this project is to study 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 valid algorithms to utilize Medicare inpatient and outpatient data to define and study the treatments received and outcomes associated with the use of BCT with radiotherapy, BCT without radiotherapy, and mastectomy in older women with local or regional breast cancer.

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

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

To accomplish these aims, we have proposed methods for utilizing Medicare inpatient, and outpatient claims data bases, as well as a data base consisting of Medicare claims linked to the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) tumor registry information.

Hypotheses

1. It will be possible to develop valid algorithms to utilize Medicare inpatient and outpatient data to define and study the treatments received and outcomes associated with the use of BCT with radiotherapy, BCT without radiotherapy, and mastectomy in older women with local or regional breast cancer.

2. Increased age (within the 65 and older age group), lower socioeconomic status, region of the country, and increased distance from a radiotherapy site with function as predictors of lack of receipt of radiotherapy among patients in receiving BCT.

3. Women who undergo BCT without radiotherapy will have an increased occurrence of treatment for local/regional disease recurrence and a greater number of cumulative inpatient days, compared to women who undergo mastectomy or BCT with radiotherapy. Overall survival will not be influenced by receipt of BCT without radiotherapy once adjusted for comorbid diseases.

6.) BODY

General Overview

Project work in the first year has centered around Phase I of the methods as described in the original proposal. This phase involved initially the acquisition and cleaning of SEER tumor registry data for women with breast cancer aged 65 and older, which has been linked to Medicare claims records. Development of an algorithm using solely Medicare data to identify and classify the linked SEER patients according to 1) incident case of breast cancer, 2) stage of disease, and 3) initial surgical treatment (mastectomy vs BCT) has also proceeded foreward.

The "updated" SEER-Medicare linked data described in the original proposal has been acquired, although some delay was encountered. The updated data include SEER patients with new breast cancer diagnoses through 1993, and Medicare claims for patients through the 1994 calendar year. We find that the linkage rates now approach 94%, slightly higher than the 93% estimated in the original proposal.

In addition, we are pleased to report that we have obtained Medicare claims for a 5% sample of Medicare beneficiaries residing in the countries covered by the SEER Registry program. The sample has been purged of cancer patients by NCI personnel, by crossing it with the SEER Registry files. Therefore, this sample can be considered to consist of non-cancer containing population-based controls for the SEER population. The acquisition of this data will permit us to directly assess the specificity and positive predictive value (PPV) of the algorithms we are developing to predict breast cancer cases, stage, and treatment. This is an enhancement to the original proposal, which required indirect methods to estimate these characteristics of the algorithm. Methods for analyzing these data will be specified in this and future reports.

Algorithm Development - Sensitivity and Discrimination of Basic Algorithms.

Methods

We began with all SEER women having a breast cancer diagnosis in 1992 who were also "linked" to the Medicare population. From this group we selected the subset of women 65-79 at time of their diagnosis in 1992, having local or regional breast cancer, with a SEER record of either mastectomy or breast conserving therapy and who were eligible for Medicare Part A and Part B service during all of 1992. Any woman having any HMO experience in 1992 or who was not age 65 or older for the entire year of 1992 was then deleted. This procedure led to the selection of 4,391 women and define our study population.

Medicare Part A inpatient (Medpar) records, Medicare Part B records and records from the "Standard Analytic File (SAF)" for 1992 were then analyzed for to determine treatment experience (based on standard ICD-9-CM coding for bilateral and unilateral mastectomy, incisional and excisional biopsy and axillary nodal dissection) and stage (local/regional) based on standard ICD-9-CM diagnostic codes (Refs. 1-4). Multiple claims were summarized by recording only the most extensive disease stage and most invasive therapy for each subject. Concordance between the SEER and Medicare classifications were summarized with diagnostic accuracy and predictive measures taking the SEER classification as the "gold standard". Estimates of sensitivity of the Medicare classifications are with respect to the entire SEER cohort, whether or not Medicare claims were actually

present. However, predictive values presented are with respect to the subset of the SEER cohort for which Medicare claims were available.

Results and Discussion

Results are presented stratified by source of claims used: Medpar (Part A) inpatient only or Medpar plus Part B (physician claims) plus Outpatient Standard Analytic File (SAF).

Table 1a shows the sensitivity of Medpar data alone for identifying SEER mastectomy and BCT patients. Medpar identifies over 87% of mastectomy cases. However, Medpar claims identify only slightly fewer than half the BCT patients. The "PPV" in this table is for discrimination of one surgical therapy vs the other, given that the patient had one or the other therapy according to SEER (i.e., all patients have breast cancer). This is not the same as the PPV for determining an incident case of breast cancer, which will be determined using the population-based control patients (non of whom have breast cancer). One can see from Table 1a that the ability to accurately discriminate surgical therapy is >93% for both mastectomy and BCT patients, given that any Medpar surgical claim is present.

Table 1b shows similar statistics for data derived from all 3 Medicare sources (Medpar inpatient + physician Part B + Outpatient SAF). The sensitivity for mastectomy cases is about the same as using Medpar data alone (reflecting the fact that the vast majority of mastectomy patients generate inpatient records). The sensitivity for BCT is much improved compared to Medpar alone, reflecting the substantial numbers of BCT patients for whom only outpatient claims are generated. The "PPV" for determination of type of surgical treatment remains >91% for Medicare cases predicted as undergoing mastectomy or BCT.

Tables 2a and 2b provide data regarding the categorization of stage of disease based on Medicare claims vs SEER information. Again, Table 2a shows the categorization based on only inpatient Medpar claims. The sensitivity for determining local disease is modest, due mainly to lack of inpatient claims for local stage patients. The sensitivity for regional disease is also modest , due partly to a lack of inpatient claims, but more to misclassification of regional cases as local (no ICD-9 diagnostic code for axillary lymph node metastases). Some of these patients may be misclassified due to axillary node pathology not being completed by the time of hospital discharge. Table 2b shows that the Part B and SAF data improve the sensitivity for local disease, but sensitivity for regional disease continues to be problematic, due to misclassification of disease as local or as distant.

Table 3a and 3b provide data regarding the classification of mastectomy vs BCT treatment by Medicare data for the subset of cases categorized as local or regional by Medicare data. Sensitivity for mastectomy is high among this subset, and sensitivity for BCT moderately high. "PPV's" are in the range of 97% for mastectomy and 92-94% for BCT.

Analysis of misclassified cases reveals useful trends by SEER month of diagnosis (Table 4). When SEER indicates mastectomy and Medicare surgical claims are absent, there is an excess of patients diagnosed in December. Such patients may actually be treated in the next calendar year. This is also true, but to a lesser extent, for cases where SEER indicates BCT and Medicare surgical claims are absent.

Use of Population-Based Non-Cancer Control Data

As mentioned above, an enhancement of our original methods will be the use of the 5% sample of the non-cancer population to directly measure the specificity and PPV of our algorithms when applied to a general population of non-cancer-containing Medicare

beneficiaries. These data were only received recently, and are quite voluminous. The data were sent on 155 9-track computer tapes, some of which were physically damaged during shipment and required replacement. We have been working to read in and process these data, but have not yet performed analyses. However, we specify here some methods required for the specificity and PPV estimation, and with the eventual effect of these algorithm characteristics on specific aim #2, the determination of outcomes class, for the cohort of Medicare patients identified by this algorithm.

Due to the low incidence of breast cancer in the general population, an extremely high specificity is required to generate PPV's in the range of 70-80% for the identification of incident cases of breast cancer. Table 5 shows the relationship of specificity to PPV for various specificity levels. A specificity of 99.9% would be required to attain a PPV of 80% in the identification of cases.

How will misclassification of the treatment undergone by cohort patients affect specific aim #3, the assessment of outcomes associated with BCT without RT vs BCS without RT vs mastectomy? In general, the effect is to decrease the ability to observe a difference in outcomes by treatment received. For example, assume the outcome of interest is treatment for local/regional disease recurrence. Based on the randomized trials as cited in the original proposal, the expected rate at 5 years might be 10% for patients undergoing mastectomy, and about 30% for patients undergoing BCS without RT. Table 6 provides estimates of the apparent difference in outcomes between the two groups when the true difference is 0.2 (BCT recurrence rate of 0.3 vs mastectomy recurrence rate of 0.1), depending on varying sensitivities and predictive values for predicting mastectomy and BCT treatment. In general, the sensitivity for both mastectomy and BCT cases must be > 90% for the apparent difference in recurrence rates to be within 5-6% of the true difference of 20%. The direction of the bias is always to underestimate the true difference in outcomes between the treatment groups.

Once we are able to work with the population control data, we will have a better idea of the likelihood that the algorithm can be optimized sufficiently to meet our needs. As noted in the original proposal, if the algorithm for using Medicare data alone cannot be optimized sufficiently, we will still be able to carry out specific aims #2 and #3 using the SEER Medicare linked data. This will provide a geographically more limited cohort, but still be population-based.

Table 1a. Breast-conserving Treatment: Medicare Part A versus SEER

	SEER	
Medicare Part A	Mastectomy	BCT
Mastectomy	2459	67
BCT	48	701
missing *(no surgical claim)*	309	807

Mastectomy:	2459/2816 = 87.3%
BCT:	701/1575 = 44.5%
PPV mastectomy:	2459/2526 = 97.3%
PPV BCT:	701/749 = 93.6%

(Proprietary data)

Table 1b. Breast-conserving Treatment: Medicare Parts A, B, and SAF versus SEER

	SEER	
Medicare Parts A, B, SAF	Mastectomy	BCT
Mastectomy	2496	70
BCT	111	1204
missing	209	301

Mastectomy:	2496/2816 = 88.6%
BCT:	1204/1575 = 76.4%
PPV mastectomy:	2496/2566 = 97.3%
PPV BCT:	1204/1315 = 91.6%

(Proprietary data)

Table 2a. Extent of Disease: Medicare Part A versus SEER

	SEER historic stage, 1992	
Medicare Part A	local	regional
in situ	54	0
local	2186	231
regional	27	744
distant	23	81
missing	894	151

Sensitivity for
Local: 2186/3184 = 68.7%
Regional: 744/1207 = 61.6%
PPV for
Local: 2186/2417 = 90.4%
Regional: 744/771 = 96.5%

(Proprietary data)

Table 2b. Extent of Disease: Medicare Parts A, B, and SAF versus SEER

	SEER historic stage 1992	
Medicare Part A, B & SAF	local	regional
in situ	39	0
local	2615	250
regional	30	722
distant	147	167
missing	353	68

Sensitivity for
Local: 2615/3184 = 82.1%
Regional: 722/1207 = 59.8%
PPV for
Local: 2615/2865 = 91.3%
Regional: 722/752 = 96.0%

(Proprietary data)

Table 3a. Breast-conserving Treatment: Medicare Part A versus SEER Cases Classified as Local or Regional by Medicare Part A

	SEER	
Medicare Part A	Mastectomy	BCT
Mastectomy	2323	65
BCT	39	658
missing	12	92

Mastectomy:	2323/2374 = 97.9%
BCT:	658/814 = 80.8%
PPV mastectomy:	2323/2387 = 97.3%
PPV BCT:	658/697 = 94.4%

(Proprietary data)

Table 3b. Breast-conserving Treatment: Medicare Part A, B and SAF versus SEER Cases Classified as Local or Regional by Medicare Part A or B or SAF

	SEER	
Medicare Part A, B, & SAF	Mastectomy	BCT
Mastectomy	2250	60
BCT	91	1102
missing	40	74

Mastectomy:	2350/2381 = 94.5%
BCT:	1102/1236 = 89.2%
PPV mastectomy:	2250/2310 = 97.4%
PPV BCT:	1102/1193 = 92.4%

Table 4. SEER Indicates Mastectomy, Medicare Part A, B, and SAF Missing

Diag. month, 1992	Freq.	Percent	Cum. Percent
1	14	6.70	6.70
2	13	6.22	12.92
3	10	4.78	17.70
4	10	4.78	22.49
5	10	4.78	27.27
6	9	4.31	31.58
7	8	3.83	35.41
8	12	5.74	41.15
9	17	8.13	49.28
10	16	7.66	56.94
11	19	9.09	66.03
12	71	33.97	100.00
Total	209	100.00	

 (Proprietary data)

Table 5. Specificity vs Positive Predictive Value for Identifying Older Breast Cancer Patients*

OBS	Specificity	PPV
1	0.9750	0.138
2	0.9755	0.140
3	0.9760	0.143
4	0.9765	0.145
5	0.9770	0.148
6	0.9775	0.151
7	0.9780	0.154
8	0.9785	0.157
9	0.9790	0.160
10	0.9795	0.163
11	0.9800	0.167
12	0.9805	0.170
13	0.9810	0.174
14	0.9815	0.178
15	0.9820	0.182
16	0.9825	0.186
17	0.9830	0.191
18	0.9835	0.195
19	0.9840	0.200
20	0.9845	0.205
21	0.9850	0.211
22	0.9855	0.216
23	0.9860	0.222
24	0.9865	0.229
25	0.9870	0.236
26	0.9875	0.243
27	0.9880	0.250
28	0.9885	0.258
29	0.9890	0.267
30	0.9895	0.276
31	0.9900	0.286
32	0.9905	0.297
33	0.9910	0.308
34	0.9915	0.320
35	0.9920	0.344
36	0.9925	0.348
37	0.9930	0.364
38	0.9935	0.381
39	0.9940	0.400
40	0.9945	0.422
41	0.9950	0.445
42	0.9955	0.471
43	0.9960	0.501
44	0.9965	0.534
45	0.9970	0.572
46	0.9975	0.616
47	0.9980	0.728
48	0.9985	0.728
49	0.9990	0.800

*Specificity within +/- .001 PPV assumes perfect sensitivity and 4/1,000 incidence.

(Proprietary data)

Table 6. Actual vs Apparent Outcomes, Based on Misclassifications of Treatment Groups.*

Sensitivity Mastectomy	Sensitivity BCT	PV Mastectomy	PV BCT	Actual Difference	Apparent Difference Recurrence Rate
0.800	0.400	0.80000	0.40000	0.2	0.04000
0.800	0.700	0.88889	0.53846	0.2	0.08547
0.800	0.800	0.92308	0.57143	0.2	0.09890
0.800	0.900	0.96000	0.60000	0.2	0.11200
0.800	0.999	0.99958	0.62477	0.2	0.12487
0.850	0.400	0.80952	0.47059	0.2	0.05602
0.850	0.700	0.89474	0.60870	0.2	0.10069
0.850	0.800	0.92727	0.64000	0.2	0.11345
0.850	0.900	0.96226	0.66667	0.2	0.12579
0.850	0.999	0.99961	0.68944	0.2	0.13781
0.900	0.400	0.81818	0.57143	0.2	0.07792
0.900	0.700	0.90000	0.70000	0.2	0.12000
0.900	0.800	0.93103	0.72727	0.2	0.13166
0.900	0.900	0.96429	0.75000	0.2	0.14286
0.900	0.999	0.99963	0.76905	0.2	0.15374
0.999	0.400	0.83319	0.99256	0.2	0.16515
0.999	0.700	0.90901	0.99573	0.2	0.18095
0.999	0.800	0.93744	0.99626	0.2	0.18674
0.999	0.900	0.96771	0.99668	0.2	0.19288
0.999	0.999	0.99967	0.99701	0.2	0.19933

* Assume True Local Recurrence Rate after Mastectomy is 0.1 and True Local Recurrence Rate after BCT is 0.3.

(Proprietary data)

7.) CONCLUSIONS

When using Medicare claims to select a cohort of older women undergoing surgical treatment for local or regional breast cancer, the sensitivity for BCT cases is substantially lower than for mastectomy cases. The 4/1000 incidence rate of breast cancer in the general Medicare population implies that very high algorithm specificity will be required. Further algorithm development will require considerable optimization of the specificity, particularly for BCT cases, to avoid unacceptably low PPV's.

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9.) APPENDICES

Department of Defense Abstract.

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EXTENDED ABSTRACT (SINGLE SPACE).

ACCURACY OF INPATIENT MEDICARE CLAIMS FOR BREAST CANCER THERAPY DETERMINATION

Craig A. Beam and Ann B. Nattinger

Divisions of General Internal Medicine and Family and Community Medicine, Medical College of Wisconsin, Milwaukee, WI 53226

EXTENDED ABSTRACT. BEGIN SINGLE SPACE 2-PAGE ABSTRACT BELOW THIS LINE. DO NOT EXCEED 2 PAGES OF TEXT.

Introduction: It is reasonable to expect that the Surveillance, Epidemiology, and End Results (SEER) registry provides almost complete ascertainment of individuals treated for breast cancer and reliable determination of therapies received. However, this is true only for the limited population of women captured by the SEER registries. Medicare data provides an alternate source of breast cancer treatment information that has the advantage of greater population coverage. The purpose of this study was to determine the accuracy of Medicare claims in determining breast cancer therapy.

Experimental Procedures: We began with all SEER women having a breast cancer diagnosis in 1992 who were also "linked" to the Medicare population. From this group we selected the subset of women 65-79 at time of their diagnosis in 1992, having local or regional breast cancer, with a SEER record of either mastectomy or breast conserving therapy and who were eligible for Medicare Part A service during all of 1992. Any woman having any HMO experience in 1992 was then deleted. This procedure led to the selection of 4,594 women and define our study population.

Medicare Part A inpatient (Medpar) records for 1992 (and 1991 if available for those having data from 1992) were then analyzed for to determine treatment experience (based on standard ICD-9-CM coding for bilateral and unilateral mastectomy, incisional and excisional biopsy and axillary nodal dissection) and stage (local/regional) based on standard ICD-9-CM diagnostic codes. Concordance between the SEER and Medicare classifications were summarized with diagnostic accuracy and predictive measures taking the SEER classification as the "gold standard". Estimates of sensitivity of the Medicare classifications are with respect to the entire SEER cohort, whether or not Medpar claims were actually

LIST UP TO 5 KEYWORDS. TYPE "KEYWORDS:" FOLLOWED BY UP TO FIVE KEYWORDS.

Keywords: Breast Cancer, Surgical Treatment, Sensitivity, Predictive Value, Medicare.

BEGIN CONTRACT ACKNOWLEDGMENT HERE ON PAGE 1.

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present. However, predictive values presented are with respect to the subset of the SEER cohort for which Medpar claims were available.

Summary of Results To Date:

Determination of breast cancer treatment based on standard Medicare surgical codings was unavailable for 925 (20.1%) women in the SEER study population because they had no Medpar data. Thus, 3,669 (80.9%) women had both SEER and Medpar data. The absence of Medicare data was significantly associated with breast cancer treatment (Pearson chi-square $p<.001$): while the majority (71%) of those without Medpar had received some form of breast conserving therapy, the majority of those with Medpar data received mastectomy (73%). The absence of Medpar data was also significantly inversely associated with age ($p=0.033$). However, the trend with age was not clinically significant: percentage of women with Medpar rose only slightly across the 3 age groups (65-69,70-74 and 75-79) from 78.3% to 82.1%. The presence or absence of Medpar data was not found to be associated with race ($p=0.583$).

About 8% (297) of the women had none of the standard surgical procedure codes listed above and are treated as "indeterminate" findings and count against the determination of diagnostic accuracy and predictive value described below. Including patients with no 1992 Medpar data, Medicare had a sensitivity of 86.2% in determining mastectomy treatment. Taking all other surgical codes listed above to indicate breast conserving therapy, Medicare had a sensitivity of 43.6% for breast conserving therapy. Among the cohort patients with a Medpar claim, the predictive value of a Medicare determination of treatment by mastectomy was 97.3%, and the predictive value of a Medicare determination of breast conserving therapy was 93.5%.

Using a conservative diagnostic coding, the Medpar data had a sensitivity of 63.4% in determining regional stage disease and a 76.5% sensitivity for local disease. Associated predictive values were 96.6% (for regional disease) and 88.8% (for local disease). A less conservative coding led to little gain: sensitivity for regional disease of 65.1% and sensitivity for local disease of 76.4%, with associated predictive values of 96.6% for regional disease and 89.4% for local disease.

Conclusions: Standard inpatient Medicare claims are of limited use in determining surgical breast cancer treatment because a large percentage of women receiving breast cancer treatment do not have inpatient claims data. To be useful, this information will have to be augmented. In future work, we will explore the gain to be had by incorporating outpatient and Part B Medicare claims.

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