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Hospital-based health care use correlates with incidence of adverse events among elderly Medicare patients treated in adjuvant chemotherapy trials (Alliance 70802)

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ABSTRACT

Objective: Medicare claims can be useful in chemotherapy-related comparative effectiveness research (CER) estimating survival, but methods for estimating patients' treatment morbidity are currently lacking. We sought to determine if patients' health care use in the claims is a marker of treatment morbidity.

Materials and Methods: For 249 elderly Medicare patients with breast or colon cancer who were treated in two adjuvant clinical trials, we merged patients' National Cancer Institute Common Toxicity Criteria for Adverse Events (CTC AEs) trial data with their contemporaneous Medicare claims. We estimated associations of patients' grade ≥3 CTC AE counts and their use of two types of hospital-based health care in claims (i.e., emergency room (ER) visits and hospitalizations).

Results: ER visits and hospitalizations were significantly positively associated with grade ≥3 CTC AE counts incurred by patients during the study. Eight percent of patients without any grade ≥3 CTC AEs had one or more hospitalizations during the observation period compared to 43% of patients with three or more grade ≥3 CTC AEs ($p < 0.01$). Those who were hospitalized at least once had more than three times the rate of grade ≥3 CTC AEs (IRR 3.70, 95% CI: 2.53–5.40) compared to those who were not. With each hospitalization, the daily incidence rate of any grade ≥3 CTC AE more than doubled (IRR 2.10, 95% CI: 1.54–2.86).

Conclusions: Because hospitalization is strongly associated with clinically significant toxicity it may be a useful outcome for Medicare claim-based CER comparing treatment morbidity for elderly patients receiving different adjuvant chemotherapy regimens.

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1. Introduction

Medicare spends billions of dollars annually on chemotherapy for elderly patients with cancer, but surprisingly little is known about the extent to which cancer chemotherapies help or harm such elderly patients.[1,2] This unsettling paradox is the direct result of the well-described under-enrollment of elderly patients with cancer in clinical trials of chemotherapy.[3–5] The dearth of realistic estimates of chemotherapy-related survival and toxicities hinders community oncologists as they discuss with elderly patients the risks and benefits of chemotherapy use, compromising patient–physician decision-making.[6,7]

Population research using observational data sources for comparative effectiveness research (CER) has the potential to yield estimates of the benefits and risks of treatment for patients with cancer who are traditionally underrepresented in clinical trials. Overall survival is well measured in Medicare data, but post-treatment morbidity is not. Some researchers have posited that International Classification of Disease 9th Revision (ICD-9) diagnostic codes provide valid estimates of post-treatment toxicities affecting elderly usual care patients.[8–15] Other research suggests that this is not the case; we found that Medicare ICD-9 diagnostic and procedure codes were poor measures of the common and clinically significant toxicities classified as grade ≥3 Common Terminology Criteria for Adverse Events (CTC AEs), a gold-standard measure of toxicity.[16] This finding motivated our search for alternative indicators of severe morbidity in elderly patients with cancer who are receiving chemotherapy (i.e., intercurrent morbidity) using Medicare data. Were reliable methods developed, such morbidity could be studied as a salient endpoint in Medicare-based CER.

We chose to study hospital-based health care use under Medicare because it is (1) a clinically meaningful measure of severity of illness (i.e., lesser illnesses can be treated in the outpatient setting), (2) something most elderly patients wish to avoid,[17,18] (3) a risk factor for iatrogenic processes including life-threatening infections,[19] (4) a risk factor for functional decline,[20] (5) easily measured in Medicare data, and (6) being used empirically in Medicare-based CER of adjuvant chemotherapy regimens as a measure of treatment-related toxicity.[21] Specifically, we assess elderly Medicare patients treated on two adjuvant chemotherapy trials for breast and colon cancer and evaluate for associations between the burden of CTC AEs they incurred while in the clinical trials and the amount of hospital-based health care they used during the same period. We hypothesized a positive association between standard clinical trial metrics of treatment toxicity and hospital-based health care use during the clinical trial period.

2. Methods

2.1. Data and Cohorts

2.1.1. CALGB Data

We used clinical trial data from the Cancer and Leukemia Group B (CALGB) to identify elderly clinical trial patients treated in the experimental setting with standard first-line adjuvant chemotherapy on CALGB breast and colon cancer trials (CALGB 49907 and 89803).[22,23] The CALGB, now a part of the Alliance for Clinical Trials in Oncology, was an NCI-sponsored cooperative oncology research group representing a network of over 3000 physicians from 29 academic medical centers and 225 community hospitals. Members of multi-modality treatment programs in seven disease areas developed therapeutic trials, which were opened for patient accrual at CALGB institutions. Data from trials are maintained centrally. Registration variables common to all therapeutic trials include study number, subject identifiers, demographic and disease information, treatment information (e.g., drugs administered, dates of treatment, CTC AE information) and survival endpoints.

The CTC AE is the standard metric of chemotherapy-related toxicity used in clinical trials nationally. The taxonomy requires identification of a category of toxicity and within the category a numeric grade of severity of the toxicity, ranging from 1 (mild toxicity) to 5 (death).[24] CTC AEs graded 3 or higher are considered clinically important and for this reason reports of clinical trial results usually include the proportion of patients with grade ≥3 CTC AEs by type (e.g., neutropenia or diarrhea).

2.1.2. Medicare Data

Medicare is a federally sponsored health insurance program administered by the Centers for Medicare and Medicaid Services (CMS) whose beneficiaries include more than 96% of all US citizens aged 65 and older.[25] CMS maintains billing records of outpatient, inpatient, home health, hospice, durable medical equipment, and other claims for all beneficiaries not enrolled in risk contract health maintenance organizations (HMOs). Of note, Medicare reimburses providers for costs associated with clinical trials including those of drugs and drug combinations that have been previously established to be standards of care. All regimens we studied were standard chemotherapy regimens at the time of trial enrollment.

2.1.3. Cohort Construction

We identified all study subjects who enrolled in the standard arm of CALGB 49907 or either the standard or experimental arm of 89803. CALGB 49907 studied women aged 65 and older with loco-regional breast cancer who were randomized to post-operative adjuvant chemotherapy with one of two standard chemotherapy regimens (i.e., the combination of doxorubicin and cyclophosphamide or the combination of cyclophosphamide, methotrexate, and fluorouracil) vs. the experimental arm (i.e., oral capecitabine). We study only patients treated on the standard arm as capecitabine is not reliably measured in claims.[22] CALGB 89803 studied patients with loco-regional colon cancer who were randomized to post-operative adjuvant chemotherapy with standard fluorouracil and leucovorin vs. fluorouracil, leucovorin, and irinotecan.[23] The Appendix (page 2) contains a detailed description of patient eligibility for each trial. For the 479 CALGB patients who were (1) Medicare eligible based on age and (2) treated at centers that were reimbursed by Medicare, we were able to match 406 (85%) to CMS Medicare claims files from the corresponding calendar period using Social Security numbers. The linked data set contained both CALGB clinical trial data (e.g., demographic information, study arm, and CTC AE information) and Medicare

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