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Title: Comorbidity, toxicity and breast cancer survival among women on and off clinical trials

Structured Abstract

The methodology to compare experimental to standard therapies through large, randomized clinical trials in a network of large cooperative oncology groups has been refined and improved over decades. The result has been significant improvements in patient survival, and a dramatic increase in the number of cancer survivors in the U.S, especially survivors of breast cancer.[1] Such trials routinely capture detailed patient information on prognostic factors for eligibility, detailed treatment information, short term acute toxicity and adverse effect information, cancer recurrence dates and dates of death. However, the ascertainment of long-term and late effects of treatment is often a challenge. Long-term toxicities require the evaluation of large numbers of patients and may occur years following the primary treatment. Thus, the assessment of long-term toxicities prospectively is typically prohibitively expensive. Furthermore, few adult cancer patients participate in trials (<3%). Patients are often excluded because they do not meet the trial's eligibility criteria, which may result in an underestimation of the true efficacy and toxicity in the general population. For this award we will use the SWOG-Medicare and SEER-Medicare linked databases (1) to evaluate the impact of baseline comorbidity (diabetes, hypertension, COPD, hypercholersterolemia) on toxicity, survival and healthcare utilization among elderly women with breast cancer treated on SWOG clinical trials. (2) To compare outcomes (toxicity, survival and healthcare utilization) between elderly patients without chronic comorbid conditions treated on SWOG clinical trials to a matched cohort of elderly patients without chronic comorbid conditions treated in the community. (3) To compare outcomes (toxicity, survival and healthcare utilization) between elderly patients with chronic comorbid conditions treated on SWOG clinical trials to a matched cohort of elderly patients with chronic comorbid conditions treated similarly in the community. The results of these analyses will lead to a better understanding of the impact of comorbidity on breast cancer outcome, and a better understanding of clinical trial generalizability.