A gradual shift in international demographics is resulting in an increasing number of elderly breast cancer patients, and this trend will accelerate with the aging of “Baby Boomers.” A critical factor in clinical research in the elderly is the impact of comorbidity on noncancer mortality and the side effects and toxicity of antitumor therapy. Unfortunately, older women have been under-represented in cancer clinical trials, and very few studies have specifically focused on these patients. A recently activated groundbreaking CALGB randomized Phase III adjuvant study will randomize women over age 65 to either capecitabine or CMF/CA in an attempt to define a less toxic and more convenient adjuvant regimen.

LACK OF ELDERLY WOMEN IN CLINICAL TRIALS

Eldey women are typically not enrolled in clinical trials. In the SWOG study of elderly patients, published in the New England Journal of Medicine in 1999, Laura Hutchins showed that although “elderly” women comprise 49% of the breast cancer cases in the United States, women over age 65 comprised only 9% of the participants in the SWOG breast cancer trials. We need to increase awareness that women older than 65 can tolerate therapy as well as women younger than 65, that they can derive benefit from treatment as long as their end-organ function is good, and that they should not be excluded from the major clinical trials.

EFFECT OF AGE BIAS IN OFFERING CLINICAL TRIAL PARTICIPATION TO OLDER PATIENTS

A lot of physicians in practice, including medical oncologists, have age biases. Many of our trials in the past had age cutoffs. Now 70-year-old women play tennis. We did a study in the CALGB and found that older women were offered trials much less frequently than younger women, but when older woman were offered participation they went on with the same frequency. The data support that older women who are in relatively good health tolerate treatments like chemotherapy, surgery and radiation therapy as well as their younger counterparts. So, physicians need education to overcome these biases.

REASONS FOR LACK OF ELDERLY PATIENTS ENROLLED IN CANCER TRIALS

“Why are the rates of enrollment of elderly patients in trials of treatment for cancer disproportionately low? The reasons include misconceptions about the benefits of enrollment in clinical trials for older patients on the part of the patients themselves, their family members, or their physicians; stringent eligibility criteria; coexisting medical conditions; and logistic barriers.

Clinicians and patients and their families may assume that older patients with cancer are not likely to tolerate or benefit from treatment in clinical trials. They may consider these studies too ‘experimental’ or the treatments too toxic or otherwise inappropriate for older patients. In a survey of American oncologists, 80% of the respondents agreed with published data showing that patients have better outcomes when they receive treatment in clinical trials, but 50% indicated that they declare patients unsuitable for clinical trials on the basis of age alone…

By 2030, the number of persons in the United States over the age of 65 years will have doubled, and the number of persons over the age of 85 years will have quadrupled. Because of the relatively high risk of cancer in these populations, we predict a high prevalence of cases of cancer in older members of the US population in the future. It may not be premature to implement prospective trials in order to determine why the rates of enrollment of elderly patients in cancer trials are low, to study and modulate the biologic features of cancer in older patients and to design therapy for otherwise fit older patients with cancer.”


SELECT PUBLICATIONS


Copyright © 2020 R. Cochrane, Inc. All rights reserved. Positive information is for educational purposes only and not to be used in patient care. Please see full prescribing information and precautions.