Recruiting more elderly patients for clinical trials

Because the majority of cancer patients are over age 65, most payments for their care emanate from the Centers for Medicare & Medicaid Services (CMS). Payments to physicians by CMS for collecting data on treatment side effects and for measuring quality care and the appropriateness of treatment guidelines are certainly relevant to the study of elderly patients with cancer. But in a recent interview with *Community Oncology* [September/October 2005], Dr. Peter Bach, a senior CMS adviser on healthcare quality and cancer policy, pointed out the broad variability in appropriate treatment. This is partly due to the fact that in some circumstances the evidence available is not that convincing. Complicating matters is the heterogeneity of patients: a broad range of ages, comorbidities, and performance scores.

To provide optimal care for elderly cancer patients, we believe that there needs to be an increased emphasis on the acquisition of quality data. Only in this way can clinicians place greater faith in the data and better adhere to evidence-based information.

How can more data be acquired? We need to do a better job of designing clinical trials appropriate for elderly patients; encouraging older patients to enter those trials; collecting meaningful and clinically relevant data; and reimbursing physicians appropriately for these efforts.

The graying of America

People over the age of 65 years are the fastest growing segment of the US population, with those over 85 leading the way. By the year 2030, individuals over 65 will account for an estimated 20% of Americans. For these reasons, CMS involvement is imperative. The incidence of cancer rises with age and is now the leading cause of death among people younger than 85.[1]

The *Community Oncology* interview with Dr. Bach points out that 80% of cancer patients are treated in community cancer clinics. Most of these patients maintain their levels of activity and functional status. The life expectancy of this group is significant. For example, a 70-year-old with average health has a life expectancy of 14.8 years, and even those with significant comorbidity such as a myocardial infarction have a life expectancy of 8.6 years.[2] Therefore, cure (or 5-year survival) and long-term toxicity are issues of great importance.

The older are not the younger

In spite of the aging of the population and the increased burden of the aging cancer population, there is a significant gap in our knowledge base. Many of our decisions are extrapolations of clinical trial data derived from younger populations. Our review of the PubMed database of articles published between 1983 and 2003 shows a paucity of clinical trials addressing aging and cancer, particularly when compared with breast cancer publications (see Figure 1). The literature reflects the fact that older patients are underrepresented in drug registration trials.[3] They are also under-represented in cooperative group trials.[4–6]

This low participation is partly due to the way in which clinical trials are conducted. Patients are regularly excluded because of comorbidities, the need for frequent office visits, and/or

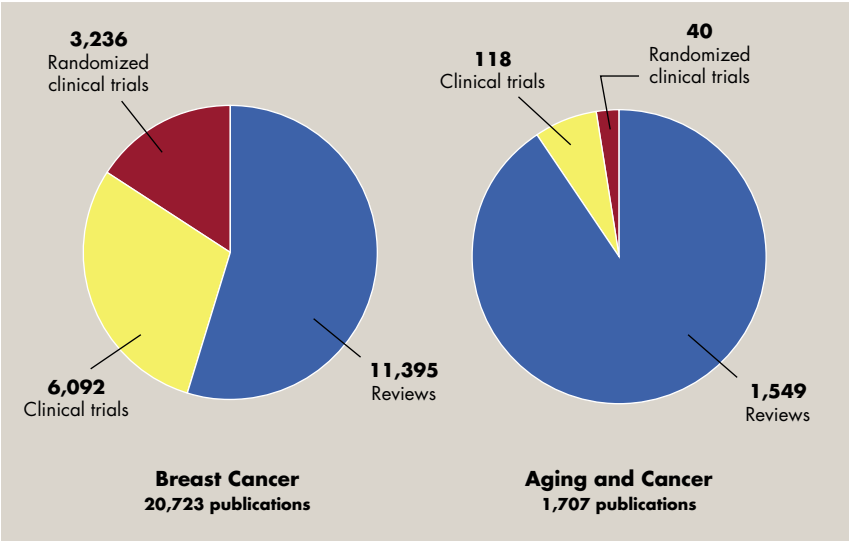

FIGURE 1 Number of medical/scientific articles published on breast cancer versus aging and cancer between 1983 and 2003. Source: Geriatric Oncology Consortium.

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increased caregiver burden. As a result, study participants often do not represent the average patient in community practice. For example, patients in the Multicenter International Study of Oxaliplatin/5-FU/Leucovorin in the Adjuvant Treatment of Colon Cancer clinical trial (MOSAIC), which led to the approval of oxaliplatin (Eloxatin) in the adjuvant treatment of colorectal cancer, had a median age of 61 years.[7] But based on SEER data, the median age of patients in the population with colorectal cancer is 72 years.

Action steps

1. Physicians need to be educated about the needs of the elderly population.

2. Patient education should emphasize the benefit of participating in clinical trials.

3. Funding sources must maintain current activities, as well as meet the needs of the future and broaden the scope of clinical trials.

4. Elderly-specific clinical trials should be designed to include a form of geriatric functional assessment to make the data relevant and clinically applicable. The measure of comorbidity is particularly important.[8]

5. Studies should include patients with comorbidities, including functional impairment and end-organ dysfunction.

In 2002, the changing epidemiology of the population, increased elderly cancer population, and lack of clinical trial data led to the formation of the Geriatric Oncology Consortium (GOC) by William Ershler, MD, and Lodovico Balducci, MD, (www.thegoc.org) with the following charge:

The mission of the Geriatric Oncology Consortium is to be the premier provider and resource for community-based geriatric oncology research and education and to fill the urgent need to address cancer treatment of the aging in a national, community-based program.

A nationwide network of 160 community research sites with more than 900 members, GOC focuses on advancing geriatric oncology research and education. It is poised to become the national voice for the older adult with cancer through patient education initiatives. GOC aims to serve as an educational resource for patients as well as the multidisciplinary team caring for these patients.

Currently, the GOC has sites in 49 states in which more than 80% are community based in hospitals and private practices. In addition, the cooperative groups and comprehensive cancer centers have organized committees and clinical trial groups to conduct studies and accumulate data. CMS funding should support these efforts. Ultimately, high-quality data will lead to high-quality, cost-effective care.

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We'd like to hear from you. Please send your instructive case reports, commentaries, and other brief communications to Randi Gould, Managing Editor, randi.gould@biolc.com.