Race and Outcomes: Is This the End of the Beginning for Minority Health Research?

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In this issue of the Journal, Dignam et al. (1) report on the outcomes of black patients with colon cancer compared with white patients with colon cancer after adjuvant chemotherapy in five randomized clinical trials. This type of analysis puts solid statistical methodology to work to answer some important societal questions. Ultimately, it helps one understand that equal treatment yields equal outcome among patients with the same stage of disease regardless of race. In combination with a number of studies with similar findings with regard to other cancers and with trials exploring other treatment modalities, it makes one realize that race should not be a factor in determining the treatment of cancer patients. A bit of history will put these statements into perspective.

In 1973, Henschke et al. (2) published a landmark paper documenting the increasing disparities in cancer mortality between black and white Americans. The Civil Rights Movement and the paper by Henschke et al. would create a public interest in minority health and especially in minority cancer health. Twenty years after the publication of the paper by Henschke et al., an appreciation that there were continuing and widening disparities among black and white Americans in a number of diseases led to the enactment into law of the NIH (National Institutes of Health) Revitalization Act of 1993. This legislation required that all NIH-sponsored phase III clinical trials include minorities and women in sufficient numbers such that a valid subset analysis could be done to ascertain differences in a treatment’s effect among women and minorities and their subpopulations (3).

This legislation and its enforcement by NIH have been the source of some controversy. An entire issue of the Journal Controlled Clinical Trials (4) was devoted to it. Statisticians and clinical trialists were concerned that there is no such thing as a statistically valid subset analysis. Some even pointed to two similar studies of adjuvant 5-fluorouracil and levamisole therapy in colon cancer patients (5,6) as examples of how subset analysis could find conflicting results. In one trial, by subset analysis, the therapy was most efficacious in younger and female patients; in the second study, it was most effective in older and male patients. A study finding a racial difference when in reality there was none could have negative consequences.

Some were concerned that the law looked to research as the answer to all of society’s problems. Others were concerned that the legislation implied that people of differing races differ biologically (7). To some the concern that a treatment’s efficacy might differ in blacks and whites harkened back to the days when the concept of “race medicine” was in vogue. This concept was the belief that a disease could behave differently in persons of one race versus another. It was, in part, the basis for the specialty of “race medicine” practiced in the United States in the 19th century and into the early 20th century (8). A hypothetical biologic difference between the races as postulated by prominent 18th century scientists was a justification for slavery and later segregation. This belief in biologic differences between races also contributed to such disgraceful acts as the U.S. Public Health Service Study of Untreated Syphilis in the Negro Male, better known as the “Tuskegee Syphilis Study” (9).

Dignam et al. (1) have addressed the legal requirement for subset analysis with innovation. Because there has been proportional representation of black cancer patients in National Cancer Institute (NCI)-sponsored cooperative group clinical treatment trials, one can combine several similar trials and have good statistical power for larger minority groups (10). Unfortunately, while Hispanic, Asian, and Native American cancer patients are proportionally represented in NCI trials, the actual number of participants is so small that the threshold number for a statistically significant analysis is not met for these groups. Studies have now been published showing that equal cancer treatment yields equal cancer outcome between blacks and whites in several cancers, including breast (11,12), prostate (13–15), and lung (16,17) cancers. The body of literature is quite compelling in teaching that race is not a biologic category.

Several of these studies, including the study by Dignam (1), do show that cancer-specific survival is equal when there is equal treatment, but overall survival remains disparate. This finding suggests that racial disparities in comorbid diseases are important to cancer control. Even though clinical trials have rigorous entry criteria, it is still likely that there are residual confounding effects of comorbid conditions (17). The National Health Interview Survey and other studies have demonstrated clear racial disparities in the rates of cardiovascular and other diseases. European studies have linked these comorbid diseases to socioeconomic status and social deprivation within race (white Europeans) (18,19). In the United States, race is a surrogate for socioeconomic status (17).

While the data show that race does not matter biologically, the literature on patterns of care also shows that, in the United States, race does matter. The study by Dignam et al. (1) and other studies like it tell us that equal cancer treatment yields equal cancer outcome, but we would be remiss if we did not mention that there are studies of colon cancer (20) and other cancers suggesting that there is not equal treatment (21–26). In one case–control cohort study (27), black patients with colon cancer were less likely than white patients to undergo surgical resection (68% versus 78%), even after controlling for age, comorbidity, location of tumor, and extent of tumor. Data on patterns of care by race are not yet available on the use of adjuvant chemotherapy in a population-based study, but there is evidence that treatment patterns do vary throughout the United States (28).

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Throughout the 1970s, the age-adjusted colorectal cancer death rate in the United States varied between 21 and 22 deaths per 100,000 for both races. Since 1980, the rates have grown more disparate; in 1996, the colorectal cancer death rate was 16.4 per 100,000 for white Americans and 22.5 per 100,000 for black Americans (29). Blacks disproportionately receive less aggressive or less appropriate therapies than whites for cancer and for a number of other diseases (30). One cannot help but hypothesize that the increasing colon cancer disparity is because medical research has found efficacious treatments and society has not disseminated these treatments equally throughout the population.

Health researchers and minority health advocates have long appreciated that a substantial part of the black–white disparity in cancer mortality is due to late stage at presentation at the time of treatment in blacks. Related to this, major efforts have been undertaken to encourage disease awareness, promote early detection, and increase minority participation in clinical trials. Such efforts must continue.

For many years, scientists have had a known that black Americans with cancer experience higher mortality compared with white Americans at the same stage of disease. A number of researchers have postulated that biologically more aggressive tumors in blacks offer the most reasonable explanation for this disparity.

However, recent data from numerous controlled clinical trials, including the current study on colon cancer, have convincingly shown that unequal treatment of blacks at curable stage of disease provides the fundamental explanation for such disparities.

This finding raises deep ethical and moral questions concerning how the research community, the American health care system, and society as a whole will move toward providing remedies for this unacceptable reality.

REFERENCES