VIEWPOINT

The Danger of Applying the ProtecT Trial to Minority Populations

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The ProtecT trial[1] has provided the medical community with Level I evidence that there is no difference in prostate cancer–specific mortality among radical prostatectomy, radiation therapy, and active surveillance at 10-year follow-up for patients with low-risk (Gleason 6) and intermediate-risk (Gleason 7) prostate cancer. Should this data be applied to all patients with low or intermediate risk prostate cancer? For some in the oncology community, it has resulted in dramatic changes in the standard of care, while others have resisted the ProtecT implications of active surveillance being comparable to radical prostatectomy or radiotherapy for patients with low-risk and intermediate-risk prostate cancer.[2,3] There are significant limitations that should be addressed with patients at the time of multidisciplinary consultation and discussion of treatment options so that patients can make the most informed decision. These limitations particularly apply to young and nonwhite patients with prostate cancer; when patients are counseled regarding the treatment-related adverse effects of definitive treatment options, they should also realize that uncertainty of outcomes beyond the 10 years of currently published results is the risk associated with active surveillance as a treatment modality.

An important but neglected aspect of the ProtecT trial[1] is its gross underrepresentation of minorities. Less than 1% of patients were of African descent, a number far smaller than the 13.8% of the US population comprised of African Americans according to the most recent US Census.[4,5] ProtecT categorized all nonwhite and all patients not of African descent as "other," and these groups comprised only 2.0% of trial patients.[4] Not surprisingly, this number is far lower than the US composition of Hispanic-Americans (12.5%) and Asian-Americans (4.1%), while arguably comparable to the 0.8% composition of Native Americans in the most recent US Census.[5] As a result, we are not confident that the ProtecT data adequately reflects the outcomes of active surveillance in these populations, particularly because some patients, such as African Americans, are known to harbor more aggressive disease than white patients.[6] Despite the fact that the ProtecT trial[1] allowed minorities to participate, the fact that only 3.0% of participants were nonwhite should limit its conclusions from being extrapolated to the racial/ethnic minority patient population, just as the mere 2.0% of ProtecT trial[1] patients who had high-risk prostate cancer has prevented the genitourinary oncology community from accepting active surveillance for high-risk patients in spite of the ProtectT results. By this same logic, active surveillance for nonwhite patients should be viewed with as much skepticism as it is currently viewed for patients with high-risk prostate cancer. Even for intermediate-risk disease (which comprised 21.0% of the ProtecT population), active surveillance is not routinely accepted among genitourinary radiation oncology experts.[7]

We believe active surveillance should not be regarded as a default management strategy for nonwhite patients with low-risk and intermediate-risk prostate cancer until a trial of comparable quality to ProtecT adequately including these populations produces long-term mortality data comparing radical prostatectomy, radiation therapy, and active surveillance.

ARTICLE INFORMATION

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