Short-term hormone therapy plus radiation therapy increases survival for men with early-stage prostate cancer

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Short-term hormone therapy (androgen deprivation therapy: ADT) given in combination with radiation therapy for men with early-stage prostate cancer increases their chance of living longer and not dying from the disease, compared with that of those who receive the same radiation therapy alone, according to a Radiation Therapy Oncology Group (RTOG) study published in the July 14 issue of the *New England Journal of Medicine*. This largest randomized trial of its kind enrolled nearly 2,000 men at low and intermediate risk of prostate cancer progression and followed their health status for more than nine years (October 1994 to April 2001) at 212 centers in the United States and Canada.

As trial co-principal investigator and RTOG Genitourinary Cancer Committee Co-Chair William Shipley, M.D. (Massachusetts General Hospital, Boston) explains, "Vigilant, long-term follow up of the enrolled patients was required due to the indolent nature of prostate cancer. With the introduction of prostate-specific antigen (PSA) testing, early detection of the disease has significantly increased; therefore, understanding the best treatment options for men with early-stage cancer is critically important." It is estimated that about 240,890 Americans will be diagnosed with prostate cancer in 2011 and almost 9 out of 10 will have early-stage disease.

All study participants had early, localized, PSA-diagnosed tumors with PSA levels of 10 to

Male hormones (androgens), the most common of which is testosterone, fuel the growth of prostate cancer cells. Therapy that decreases the body's levels of androgens (in this study, four months of ADT starting two months prior to radiation therapy) removes the strongest growth factor for prostate cancer cells. The authors report that adding short-term ADT to radiation therapy significantly improved the overall survival rate at 10 years from 57 percent to 62 percent. Furthermore, the radiation therapy plus short-term ADT arm was associated with 4 percent fewer prostate cancer-related deaths compared with the radiation therapy-alone arm (8 percent vs. 4 percent). A particularly important finding was that the reduction in disease-specific deaths was accounted for mostly by the intermediate-risk study participants in the radiation therapy plus ADT arm (10 percent vs. 3 percent in radiation only arm at 10 years) while no reduction in deaths was seen among low-risk participants at 10 years.

"These findings have tremendous significance for improving both clinical care and the utilization of health care resources." says trial co-principal investigator and lead author Christopher U. Jones, M.D. (Radiological Associates of Sacramento, Sacramento, Calif.). "We now have strong scientific evidence that adding short-term ADT to radiation therapy benefits intermediate-risk, but not low-risk, patients with early-stage prostate cancer. These benefits were achieved with a mild increase in patient-reported erectile dysfunction at one year but no increase in observed long-term bowel or bladder toxicities."

RTOG Genitourinary Cancer Committee Chair and co-author Howard Sandler, M.D., (Samuel Oschin Cancer Institute, Cedars-Sinai Medical Center, Los Angeles) comments, "In addition to establishing short-term ADT in combination with radiation therapy as the new standard of care for men with intermediate-risk prostate cancer, the results also suggest a biological interaction between the two therapies, given that several randomized trials of surgery and short-term ADT did not show a benefit

in outcome."

The authors note that the higher radiation dose and new treatment technology being employed today with demonstrated higher treatment efficacy could potentially provide the same or greater benefit as the addition of short-term ADT. "RTOG launched a trial in 2009 (see RTOG 0815) to examine the role of short-term ADT combined with modern radiotherapy techniques for men with intermediate-risk prostate cancer," says Walter J. Curran, Jr., M.D. (Winship Cancer Institute of Emory University, Atlanta), RTOG Group Chair. "The results of the RTOG 0815 trial will build on the important knowledge gained from this landmark study findings."

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