Men with Intermediate-Risk Prostate Cancer Have Excellent Outcomes and Fewer Treatment Side Effects with a Short Course of Hormonal Therapy Prior to Radiotherapy

Philadelphia—Men with prostate cancer who are at intermediate risk for cancer recurrence after initial treatment are best served with an 8-week course of androgen suppression therapy (AST), followed by radiotherapy (RT) with an additional 8 weeks of AST, according to results of the RTOG 9910 randomized clinical trial published online December 22 in the Journal of Clinical Oncology. More than 233,000 men are expected to be diagnosed with prostate cancer in 2014 with one-third or more in the intermediate-risk category.

Conducted by the Radiation Therapy Oncology Group (RTOG), now conducting research as NRG Oncology, the trial evaluated whether extending the total course of AST to 36 weeks (28 weeks prior to RT plus 8 additional weeks) improved patient outcomes. The study results showed the extended course of AST provided no additional benefit to patients. The goal of AST is to reduce levels of male hormones (or androgens) in the body that stimulate prostate cancer cell growth.

“This study provides the highest level of evidence available that more treatment is not necessarily better treatment for these patients,” says Thomas M. Pisansky, M.D., principal investigator for the RTOG 9910 phase III multicenter trial, and professor of radiation oncology at the Mayo Clinic in Rochester, MN. “Despite practice trends to increase the duration of androgen suppression therapy based on prior research, this evidence demonstrates that a short 16-week course of androgen suppression therapy provides excellent outcomes for patients with intermediate-risk prostate cancer without the increased side effects of longer androgen suppression therapy that may include hot flashes and erectile dysfunction. It’s also excellent news that we can reduce the cost of the medical therapy while maintaining excellent patient outcomes,” says Pisansky.

Nearly 1,580 study participants with intermediate-risk prostate cancer were enrolled in the RTOG 9910 trial at 152 academic and community-based research sites to test whether extended AST prior to RT would reduce disease-related deaths based upon prior RTOG study results, basic research, and observation in surgical patients demonstrating that extended AST resulted in smaller amounts of residual cancer at the time of surgery. The participants were evenly randomized to receive a 16-week total course of AST (Arm 1) or a 36-week course of AST (Arm 2).

At 10 years of follow-up, prostate cancer deaths among participants numbered 30 in Arm 1 and 24 in Arm 2. The authors report that far fewer participants died of prostate cancer than projected at the time of study design (3% prostate cancer mortality at eight years vs. 21% expected). Given the lower death rate from prostate cancer, they suggest a much larger trial (approximately 7,000 study participants) would be required to determine adequately if the longer course of AST reduced the risk of prostate cancer death—an enrollment goal that is likely unfeasible. However, Pisansky notes, “The results across all end points are so close that this study confirms we have a treatment that works very, very well. These end points include, at 10 years, comparisons of participants in Arm 1 and Arm 2 overall survival (66 percent vs. 67 percent), incidence of a rising prostate-specific antigen (PSA) level (27 percent in both Arms), locoregional prostate cancer recurrence (6 percent vs. 4 percent), and cancer metastasis rates (6 percent in both Arms).

“The work of RTOG—now NRG Oncology—investigators has led to the establishment of standards for prostate cancer care world-wide, and these results build upon that legacy by contributing important information that will positively affect patient care,” says Walter J. Curran, Jr, M.D., an NRG Oncology Group Chairman and Executive Director of the Winship Cancer Institute of Emory University in Atlanta.
NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of patients with cancer. Founded in 2012, NRG Oncology is a Pennsylvania-based nonprofit corporation that integrates the research strengths of the National Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group and the Gynecologic Oncology Group. The research organization seeks to carry clinical trials with emphases on gender-specific malignancies including gynecologic, breast, and prostate cancers and on localized or locally advanced cancers of all types. NRG Oncology’s extensive research organization is comprised of multidisciplinary investigators including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians and encompasses more than 1300 research sites located world-wide with predominance in the United States and Canada. NRG Oncology is supported primarily through grants from the National Cancer Institute (NCI) and is one of five research groups in the NCI’s National Clinical Trials Network.