Long-Term Results of the RTOG 0236 Stereotactic Body Radiotherapy Trial Confirm the Modality’s Important Role in the Treatment of Early-Stage, Medically Inoperable Non-Small Cell Lung Cancer

San Francisco—Results of the 5-year follow-up on patients who participated in the Radiation Therapy Oncology Group (RTOG) 0236 clinical trial reported today at the American Society for Radiation Oncology’s 56th Annual Meeting show good cancer control of the stereotactic body radiotherapy (SBRT)-treated area and no increase in the rate of late-appearing treatment side effects compared with results reported at 3 years of follow up. However, an increase in cancer recurrence outside of the radiation treated area was appreciated with the longer follow-up.

RTOG, which now carries out research as NRG Oncology, was the first North American cooperative group to evaluate SBRT in a clinical trial.

“For this trial, we sought patients with non-small cell lung cancer who had comorbidities such as heart disease or emphysema that precluded surgical removal of the tumor,” says trial Principal Investigator Robert Timmerman, M.D., professor of radiation oncology and neurosurgery at the University Of Texas Southwestern Medical Center in Dallas. “The previous results analyzed at 3 years posttreatment and published in 2010 were astounding. Given those exceptionally good initial results, reporting the 5-year follow-up analysis is particularly important for demonstrating whether those results were durable.” At a median follow-up of 4.0 years—and of 7.2 years for surviving patients—Timmerman reported that disease-free and overall survival were 26 percent and 40 percent, respectively, emphasizing the better-than-expected results despite the medically compromised patient population. Additionally, only 7 percent of patients experienced recurrence of the primary irradiated tumor.

With severe toxicity remaining relatively unchanged, the 5-year follow-up analysis results also allayed concerns about whether delivering a large dose per treatment (hypofractionated) of radiation using SBRT would result in late radiation side effects, such as ulcers or fistulas. “We owe this positive result to the advanced technology that really limited the potent hypofractionated radiation to just the tumor and the immediate vicinity and avoided the late effects that were so historically concerning,” says Timmerman.

There were some concerning findings with longer follow-up. For example, with an increase in locoregional cancer recurrence (from 13 percent at 3 years to 38 percent at 5 years), primarily in the lymph nodes and the involved lung lobe apart from the area irradiated, Timmerman suggests that future treatment strategies for this patient population possibly could include adjuvant systemic therapy, molecular targeted therapy, or a focus on modulation of the immune system.

“This landmark research has had a positive and significant impact on clinical practice. It has also laid the groundwork for current and future trials investigating the use of SBRT in lung cancer that hold great promise for continued improved patient outcomes,” 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.

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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 worldwide 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.