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press release

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September 12, 2014

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Embargoed Until:
Monday, Sept. 15, 2014
2:47 PM PDT

Higher-Dose Radiation Shown to Control Prostate Cancer Effectively in Patients At Intermediate Risk for Cancer Recurrence

San Francisco—The initial results of the randomized, phase III RTOG 0126 trial presented today at the American Society for Radiation Oncology (ASTRO) Annual Meeting demonstrate that higher-dose (79.2 Gy) radiotherapy (RT) vs. standard-dose (70.2 Gy) RT resulted in fewer patients experiencing prostate-specific antigen (PSA) failures, prostate cancer progression, metastases, or initial treatment failure. The study results also show that patients in the high-dose RT arm did not live longer and experienced significantly more ≥ grade 2 gastrointestinal and genitourinary side effects than patients receiving the standard dose. Patients in both study arms were treated using either 3-dimensional conformal RT (3D-CRT) or intensity-modulated RT (IMRT).

“This trial confirms that high-dose conformal radiation therapy controls prostate cancer effectively more often than the lower doses that were used in previous RTOG trials. The improvement in distant metastases indicates that local control is important to prevent the spread of prostate cancer. More patients may be spared the need for secondary or salvage therapies when they receive high-dose treatment. While we did not see an improvement in overall survival, the rate of prostate cancer death was remarkably low; only 3 percent of all patients enrolled,” reports RTOG 0126 Principal Investigator Jeff Michalski, M.D., M.B.A., FASTRO, chair of the NRG Oncology Radiation Oncology Committee and the Carlos A. Perez Distinguished Professor of radiation oncology at Washington University in St. Louis.

Research sites across the United States and Canada enrolled 1,532 patients from March 2002 to August 2008 into the clinical trial conducted by the Radiation Therapy Oncology Group (RTOG), which is now conducting research as part of NRG Oncology. Seven hundred and forty-eight eligible cases were analyzed for the 79.2-Gy arm and 751 for the 70.2-Gy arm. All cases went through rigorous quality assurance (QA), with 100 percent of the RT treatment plans reviewed for adherence to the protocol’s specifications.

“The introduction of both 3D-CRT and IMRT required credentialing of participating institutions and careful review of enrolled cases. At the time this study was started, many centers had little experience with these technologies and the Image-Guided Therapy QA Center and the Radiological Physics Center contributed to a high level of treatment quality for patients enrolled on the trial,” reports Michalski.

At a median patient follow-up of 7.0 years, the 5-year and 10-year data reported included rates of PSA failure (25 percent and 30 percent [79.2 Gy] vs. 40 percent and 45 percent [70.2 Gy]); prostate cancer progression (1 percent and 4 percent [79.2 Gy] vs. 2 percent and 8 percent [70.2 Gy]); metastases (2 percent and 5 percent [79.2 Gy] vs. 3 percent and 8 percent [70.2 Gy]); and secondary treatment after primary treatment failure (13 percent [79.2 Gy] vs. 21 percent [70.2 Gy]). Overall survival rates reported were 88 percent and 67 percent in the 79.2-Gy arm compared with 89 percent and 66 percent in the 70.2-Gy arm.

Prior RTOG and single-institution research demonstrated that patients at intermediate risk for cancer recurrence had the most to gain potentially from receiving the higher-dose RT treatment. The Eligible patients for RTOG 0126 included those with clinical stage T1b−T2b and Gleason Score [GS] 2−6 and PSA ≥10 and <20, or clinical stage T1b−T2b and GS 7 and PSA <15, with no lymph node involvement, metastases, or previous hormone treatment.

“This study, the largest randomized RT dose-escalation study in prostate cancer, confirms that higher doses of radiotherapy reduce overall treatment failure, including PSA failure and distant metastases. Based on this trial and other RTOG research, it seems clear that both improved local control through high doses of radiation and improved control of distant metastases through the appropriate use of hormonal therapy are required to optimize the treatment of prostate cancer using radiotherapy,” reports Howard M. Sandler, M.D., M.S., FASTRO, chair of the NRG Oncology Genitourinary Cancer Committee and the Ronald Bloom Chair in Cancer Therapeutics at Cedars-Sinai Medical Center in Los Angeles.

“RTOG 0126 exemplifies the type of science that NRG Oncology intends to conduct, with a focus on improving the lives of patients with localized, gender-specific cancers and pursuing promising new technology,” 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.

This project was supported by grants U10CA21661, U10CA180868, U10CA180822, U10CA37422, U24CA180803, and U24CA81647 from the National Cancer Institute.

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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 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.