Journal Highlights NCI-Sponsored Phase III Study Comparing Radiosurgery with Surgery for the Treatment of Early-Stage High-Risk, Operable Non-Small Cell Lung Cancer

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The Journal of Thoracic and Cardiovascular Surgery has published an article summarizing the goals of an ongoing phase III study comparing radiosurgery with surgery for the treatment of early-stage, high-risk, operable non-small cell lung cancer. Appearing in the September 2012 issue, the article by the study chair and co-chair explains why this randomized study "is necessary and timely."1 Stereotactic body radiotherapy (SBRT)-a radiosurgical approach that attacks lung and other tumors using carefully-shaped, high dose X-ray beams-has been shown to be effective for treating early-stage, non-small cell lung cancer in patients who can't be operated on, the authors point out.2 This group of patients is often referred to as being medically inoperable. SBRT is also sometimes referred to as stereotactic ablative body radiotherapy (SABR)3 for its "unique radiobiological characteristics that cause dramatic tumor response and high tumor control rates."4 Standard-risk operable patients with lung cancer are usually treated with surgery to remove the affected lobe (lobar resection). Patients who cannot tolerate complete removal of a lobe, but who are still considered well enough to undergo general anesthesia, often referred to as "high-risk, operable" patients, are usually treated with sublobar resection, or removal of just a portion of a lobe. "Several investigators have suggested that SBRT might be equally effective for these high-risk operable patients," says Robert Timmerman, study co-chair. "We set up this randomized study to compare SBRT, which is a non-invasive therapy, with surgery. We'll be looking at patients' overall, disease-free, and regional recurrence-free survival rates three years after treatment, and also comparing adverse events and post-treatment quality of life measures." "The primary objective of the study is to determine whether patients treated with SBRT have 3-year overall survival rates that are no more than 10% less than patients treated with sublobar resection," said Hiran C. Fernando, MD, study chairman. "Although it is certainly attractive to patients to have a less invasive therapy, with lower risks, we need to know whether this translates into better cancer control or survival." Sponsored by the U.S. National Cancer Institute (NCI), the study is being overseen by the Alliance for Clinical Trials in Oncology, an NCI-sponsored research cooperative that was formed in March 2011 from the merger of the American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB), and the North Central Cancer Treatment Group (NCCTG). Referred to as ACOSOG Z4099/RTOG1021, the study plans to accrue 420 patients over a five-year period. As of September 2012, there were 55 cancer treatment centers that had met all requirements for becoming credentialed to participate in the study.

Last month, Varian Medical Systems became the exclusive corporate supporter of

this study, specifically to support institutions, as well as the overall conduct of the trial by the Alliance for Clinical Trials in Oncology (see press release dated August 15, 2012). Varian TrueBeamT and Trilogy@ medical linear accelerator systems are among the technologies that can be used to perform SBRT procedures. Varian is not providing technology for use in the study, however, and participating institutions can use any radiosurgery system that meets the study requirements.

"We are hoping that more cancer treatment centers will complete the credentialing process and participate in the study, so that we can accrue a sufficient number of patients in a reasonable timeframe," says Dr. Fernando. "We believe that this study will help us make better decisions about when to use surgery and when to use SBRT, so that surgeons and radiation oncologists can work together more effectively to counsel patients regarding the risks and benefits of each approach." For further information, please refer to the study description on the NIH website.

About Varian Medical Systems Varian Medical Systems, Inc., of Palo Alto, California, is the world's leading manufacturer of medical devices and software for treating cancer and other medical conditions with radiotherapy, radiosurgery, and brachytherapy. The company supplies informatics software for managing comprehensive cancer clinics, radiotherapy centers and medical oncology practices. Varian is a premier supplier of tubes, digital detectors, and image processing workstations for X-ray imaging in medical, scientific, and industrial applications and also supplies high-energy X-ray devices for cargo screening and non-destructive testing applications. Varian Medical Systems employs approximately 6,000 people who are located at manufacturing sites in North America, Europe, and China and approximately 70 sales and support offices around the world. For more information, visit http://www.varian.com or follow us on Twitter.

1 Fernando HC and Timmerman R. American College of Surgeons Oncology Group Z4099/Radiation Therapy Oncology Group 1021: A randomized study of sublobar resection compared with stereotactic body radiotherapy for high-risk stage I non-small cell lung cancer. J. Thorac Cardiovasc Surg. 2012;144:S35-8.

2 Timmerman R, Paulus R, Galvin J, Michalski J, Straube W, Bradley J, et al. Stereotactic body radiation therapy for inoperable early stage lung cancer. JAMA.2010;303:1070-6.

3 Loo BW, Chang JY, Dawson LA, Kavanagh BD, Koong AC, Senan S, Timmerman RD. Stereotactic ablative radiotherapy : what's in a name ? Practical Radiation Oncology. 2011;38-39 4 Heinzerling JH, Kavanagh B, Timmerman RD. Stereotactic ablative radiation therapy for primary lung tumors. The Cancer Journal.

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