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**Symposium Press Office**
**October 30-31, 2014**
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# 10 years of data reveals excellent, sustained local control with minimal side effects for medically inoperable, early stage lung cancer patients who received high-dose rate stereotactic body radiotherapy (SBRT)

Chicago, October 30, 2014—Analysis of data from an institutional patient registry on stereotactic body radiotherapy (SBRT) indicates excellent long-term, local control, 79 percent of tumors, for medically inoperable, early stage lung cancer patients treated with SBRT from 2003 to 2012, according to research presented today at the 2014 Chicago Multidisciplinary Symposium in Thoracic Oncology. The Symposium is sponsored by the American Society of Clinical Oncology (ASCO), the American Society for Radiation Oncology (ASTRO), the International Association for the Study of Lung Cancer (IASLC) and The University of Chicago Medicine.

The 300 patients in the study had 340 lesions (tumors) and were treated from October 1, 2003 through December 31, 2012, at the Cleveland Clinic, one of the early adopters of SBRT technology for lung cancer patients in the United States. Patients in the study had a median age of 74 years (range = 37-97 years), a median Karnofsky Performance Status (KPS) of 80 (range = 40-100), and were not

candidates for surgery because of associated medical conditions, of which chronic obstructive pulmonary disease (COPD) was the most common (62 percent). Median follow-up was 17.4 months (range = 0.3-112.2 months), with 46.7 percent (140) patients alive at the time of follow-up. Median tumor diameter was 2.4 cm (range 0.1-10 cm), and 36.3 percent of tumors (123) had either no biopsy or a non-diagnostic biopsy. Fifteen percent of patients (45) received two or more SBRT treatments.

SBRT for lung cancer necessitates accurate and custom mapping of each individual patient's anatomy and a way of accounting for breathing motion to optimally target tumors while sparing as much of the surrounding healthy tissue as possible. In this study, all patients were uniformly treated using a vacuum-bag immobilization system and abdominal compression to limit breathing effects. Then, CT images were acquired to record tumor motion when at rest, full inhalation and full exhalation. These three images merged together generated the internal target volume (ITV) of the tumors, essentially representing a virtual map of tumor motion. Radiation doses were calculated to deliver ≥95 percent of the planning target volume (PTV), defined as the ITV + 5mm "safety" margin. All patients received 50 Gy in 5 fractions delivered during one week by 7-9 highly targeted radiation beams.

Early and late toxicity, as defined by the Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 was measured for all patients. The overall rate of any toxicity was 13.0 percent (45), with most patients having minimal toxicities (grade 2 or less) and no grade 4 or 5 toxicity events were recorded. The most common occurrences were chest wall toxicity, 7.7 percent, and pneumonitis (inflammation of the lung tissue), 4.1 percent. The toxicity rate for the 115 lesions classified as "central" tumors, according to the RTOG 0813 definition of "within or touching the zone of the proximal bronchial tree or adjacent to mediastinal or pericardial pleura," vs. non-central tumors (225 lesions) was 15.5 percent (18 lesions) vs. 11.7 percent (27 lesions).

At five years post-treatment, local control was 79.0 percent vs. 75.4 percent for patients with central tumors vs. non-central tumors, respectively. The distant metastases-free and disease failure-free rates were 49.5 percent vs. 56.7 percent, and 37.3 percent vs. 34.3 percent, respectively. Overall

survival was 18.3 percent vs. 20.3 percent, respectively. The failure rates of the central vs. non-central tumors utilizing all parameters had no statistically significant differences. Rates of local, lobar (within a whole lobe of the lung) and regional node failure for lesions were 11.2 percent, 4.1 percent and 13.5 percent, respectively.

"We have been privileged in demonstrating that lung SBRT can now be considered the standard of care for medically inoperable patients with early stage lung cancer," said Gregory M.M. Videtic, MD, lead study author, and a radiation oncologist at the Cleveland Clinic Foundation and associate professor of radiation oncology at the Cleveland Clinic Lerner College of Medicine, Case Western Reserve University. "Since our results indicate no unusual long term side effects, we are hoping to extend the potential uses of this therapy to more-fit, operable lung cancer patients whose cancer has not spread outside of the lung and to collaborate with other institutions on conducting such a clinical trial. SBRT could provide a more minimally invasive procedure than surgery, with fewer side effects and improved patient outcomes."

The abstract, "A Decade of "50 in 5": Maturing SBRT Outcomes for Medically Inoperable Early Stage Lung Cancer at Cleveland Clinic Over 10 Years," will be presented in detail during a poster session at 5:00 p.m. Central time on Thursday, October 30, 2014. To speak with Dr. Videtic, please call Michelle Kirkwood on October 30-October 31, 2014, in the Press Office at the Chicago Marriott Downtown Magnificent Mile at 312-595-3150, or email: michellek@astro.org.

The 2014 Chicago Multidisciplinary Symposium in Thoracic Oncology will provide a clinically relevant, multidisciplinary update on the scientific progress in treating thoracic malignancies. The symposium brings together physician specialists and practicing clinicians of the multidisciplinary care team to discuss the evolving management of thoracic cancers. The Symposium integrates scientific abstract presentations with accompanying discussions, poster abstract presentations, as well as "challenging case" presentations in interactive tumor board-style forums. The two keynote speakers for the Symposium are Kenneth Rosenzwieg, MD, FASTRO, of Mount Sinai School of Medicine in New York, and Corey J. Langer, MD, of Abramson Cancer Center in Philadelphia. Dr.

Rosenzwieg will discuss the use of mutational analysis to guide systemic therapy; and Dr. Langer will review the cutting edge, lung cancer research presented at recent national meetings – ASCO, ASTRO and STS (Society of Thoracic Surgeons).

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**2014 Multidisciplinary Symposium in Thoracic Oncology**
**News Briefing, Friday, October 31, 2014, 7:00 a.m. Central time**

Poster Presentation: Thursday, October 30, 2014, 5:00 p.m. Central time, Chicago Ballroom, Chicago Marriott Downtown Magnificent Mile

## 116 A Decade Of "50 In 5": Maturing SBRT Outcomes For Medically Inoperable Early Stage Lung Cancer At Cleveland Clinic Over 10 Years

**Authors:** G. M. Videtic, C. Reddy, N. Woody, T. Djemil, K. Stephans, *Cleveland Clinic, Cleveland, OH*

**Abstract Body:**
**Purpose/Objective(s):** To report on 10 years of experience with the first lung stereotactic body radiotherapy (SBRT) fractionation schedule used from the initiation of our institutional SBRT program.

**Materials/Methods:** We surveyed our IRB-approved prospective SBRT registry for all medically inoperable non-small cell lung cancer patients treated with 50 Gy in 5 fractions between 10/1/2003 and 12/31/2012. All patients were treated on a Novalis/BrainLAB platform using Bodyfix for immobilization and abdominal compression to limit tumor motion. Under compression, CT simulation images of tumor acquired at rest, full inhalation, and full exhalation were merged to generate an internal target volume (ITV). Dose was prescribed to cover $\geq$ 95% of the planning target volume (PTV) defined as PTV=ITV + 5 mm margin. SBRT was planned using heterogeneity corrections and delivered by 7-9 IMRT beams over consecutive days with daily Exactrac for IGRT.

**Results:** Three hundred forty lesions were treated in 300 patients, of which 15% had multiple treatments. Median follow up for survival was 17.4 months (range 0.3-112.2) and 17.8 months for living patients (range 2.1-96.7) with 46.7% of patients alive at analysis. Median age was 74 years (range 37-97); median KPS was 80 (range 40-100); 56% were female. Median FEV1 and DLCO (as % predicted) were 59 and 52. The principal co-morbidity for medical inoperability was pulmonary in 62.0% of patients, with 18.3% smoking at SBRT. Median tumor diameter was 2.4 cm (range 0.1-10); median PET SUV max was 7.6 (range 1-59); 36.2% of tumors had no or non-diagnostic biopsies. Per RTOG 0813 definition, 115 lesions (33.8%) were "central". Overall, the rate of any grade toxicity was 13.0 % (with no grades 4 or 5) and chest wall symptoms constituted 7.7%. For central versus non-central lesions, the toxicity rate was 15.5% vs. 11.7%, with chest wall toxicity constituting 5.8% vs. 8.6% and pneumonitis 5.8% vs. 3.0%, respectively. For central versus non-central lesions, five-year actuarial local control, distant metastases-free, disease failure-free, and overall survivals (in %) were 79.0 v 75.4, 49.5 v 56.7, 37.2 v 34.3, and 18.3 v 20.3, respectively. At analysis, crude rates by lesion of local, lobar and regional nodal failure (in %) were 11.2, 4.1 and 13.5, respectively. There were no statistically significant differences in the failure rates between central and non-central lesions for all parameters.

**Conclusions:** A decade's experience with Lung SBRT using 50 Gy in 5 fractions reveals excellent local control. Patterns of cancer failure are mainly distant. Co-morbidities drive mortality in this population. This schedule is effective independent of tumor location in the lung, with minimal toxicities that are location-dependent.

**Disclosures: G.M. Videtic:** None. **C. Reddy:** None. **N. Woody:** None. **T. Djemil:** None. **K. Stephans:** None.