**Press Release**

**Stereotactic Body Radiation Therapy Found Safe for Medically Inoperable Patients with Non-Small Cell Lung Cancer**

**BOSTON, MA** — Stereotactic body radiotherapy (SBRT) has been increasingly utilized for medically inoperable early stage non-small-cell lung cancer with patients with centrally located tumors receiving a lower radiation dose that what is prescribed for patients with peripherally located tumors due to normal tissue toxicity concerns. **NRG-RTOG 0813: Seamless Phase I/II Study of Stereotactic Lung Radiotherapy (SBRT) for Early Stage, Centrally Located Non-Small Cell Lung Cancer (NSCLC) in Medically Inoperable Patients** tested the safety of using SBRT at different dose levels for patients with centrally located NSCLC. NRG-RTOG 0813 tested SBRT on 110 patients with medically inoperable, centrally located NSCLC and found that higher doses could be delivered with acceptable toxicity and produce outcomes similar to patients with peripheral disease. The primarily elderly patients were accrued onto a dose-escalating five fraction SBRT schedule ranging from 10-12 Gy/fraction (fr) delivered over one and a half to two weeks. The phase I results of this trial were presented at the 2015 American Society of Radiation Oncology (ASTRO) Annual Meeting and the phase II efficacy results were presented at the 2016 ASTRO Annual Meeting in Boston, Massachusetts, on date September 25, 2016.

“Data from phase I of the trial indicated a relatively low rate of serious toxicity on the highest dose level we planned to test, 12 Gy per fraction for five fractions; the seamless study design allowed for ongoing phase II accrual at the dose closest to maximum tolerated dose”, says Andrea Bezjak, MD, of the Department of Radiation Oncology at the Princess Margaret Cancer Center in Toronto and the primary investigator of NRG-RTOG 0813. “We were pleased to see that the higher dose levels were found to be both safe and effective as compared to data from comparable SBRT trial results.”

The phase two efficacy results are based on the patients treated at the two higher dose levels: the 33 patients that were treated with 12Gy/fr (total dose 60Gy in 5 fr) and the 38 patients treated on the preceding dose level of 11.5 Gy/fr. (total dose 57.5 Gy in 5 fr)

The median follow up was 33 months for the 11.Gy/fr cohort and 29.8 months for the 12Gy/fr cohort. Late grade three or higher toxicities attributed to SBRT were two grade five toxicities for the 11.5Gy/fr cohort and in the 12Gy/fr cohort, three grade three toxicities. Two-year local control in the 11.5 Gy/fr cohort was 89.4% and in the 12 Gy/fr cohort was 87.7%. Two-year progression-free survival was 52.2% and 54.5% respectively, and two year overall survival was 70.2% and 72.7% respectively. In summary, the toxicity in the 71 patients treated at the two highest dose levels in this trial was acceptable and the local control and outcomes data comparable to SBRT results in peripherally located early stage NSCLC.

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Full Citation

Efficacy and Toxicity Analysis of NRG Oncology/RTOG 0813 Trial of Stereotactic Body Radiotherapy (SBRT) for Centrally Located Non-Small Cell Lung Cancer (NSCLC)


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