

High-dose stereotactic body radiotherapy well-tolerated by patients with centrally located lung tumors

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Stereotactic Body Radiotherapy (SBRT), a high-dose, precisely delivered radiotherapy, is considered the standard treatment for patients with medically inoperable, node-negative, non-small cell lung cancer (NSCLC). However, this well-tolerated radiation treatment was not previously tested in centrally located NSCLC due to the fact that patients with centrally located lung tumors demonstrate a higher risk for toxicity if treated with high SBRT doses.

The NRG Oncology clinical study NRG-RTOG 0813 was designed to find the maximum tolerated dose (MTD) of SBRT for centrally located NSCLC in medically inoperable patients. The seamless Phase I/II study examined a 5 fraction, dose escalating schedule of SBRT that ranged from 10 to 12 Gy/fraction delivered over 1.5 to 2 weeks in 120 accrued patients from the United States and Canada. Results of this study are published in the *Journal of Clinical Oncology*.

The MTD was the highest dose level allowed by the protocol, 12.0 Gy per fraction in 5 fractions, and was associated with a 7.2% dose-limiting toxicity (DLT), defined as any treatment-related grade 3 or worse from a list of predefined toxicity types which occurred within the first year. The DLT rate of 7.2% is significantly below the protocol-specified target rate of 20%. Treatment was also associated with high rates of tumor control.

"The patients who enrolled into NRG-RTOG 0813 were medically inoperable with early stage lung cancer, mostly elderly and with comorbidities. The two-year [overall survival](#) rates for patients at the two highest doses were 70% which is comparable to patients with peripheral early stage tumors that were treated by SBRT," stated Andrea Bezjak, MD, of the Princess Margaret Cancer Center and the lead author of NRG-RTOG 0813.

Two-year rates for the 71 evaluable patients in the 11.5Gy/fr and 12.0Gy/fr cohorts were: [local control](#) 89.4% (90% CI:81.6-97.4), 87.9% (90% CI :78.8-97.0); overall survival 67.9% (95%:50.4-80.3), 72.7% (95%:54.1-84.8); [progression-free survival](#) 52.2% (95%:35.3-66.6), 54.5% (95%:36.3-69.6).

"This trial demonstrated our ability to provide local control and potential for cure in [patients](#) with centrally located, node-negative tumors in multiple institutions, while maintaining plan qualities, achieving good patient outcomes, and only allowing modest rates of toxicity," added Dr. Bezjak.

More information: Andrea Bezjak et al, Safety and Efficacy of a Five-Fraction Stereotactic Body Radiotherapy Schedule for Centrally Located Non–Small-Cell Lung Cancer: NRG Oncology/RTOG 0813 Trial, *Journal of Clinical Oncology* (2019). [DOI: 10.1200/JCO.18.00622](https://doi.org/10.1200/JCO.18.00622)

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