

Phase 1 trial of patients with NSCLC will evaluate paclitaxel and carboplatin plus hypofractionated RT, or paclitaxel plus carboplatin after RT is completed. The primary outcome is the maximum tolerable RT dose fraction in the concurrent arm.

Dr. De Ruyscher concluded by stating that in his opinion, the most optimal nonconcurrent RT at this time is using an accelerated schedule. For concurrent chemoradiotherapy, the standard regimen should be retained at this point, as decreasing the overall treatment time with RT has not yet been demonstrated to improve outcomes.

Stereotactic Body Radiation Therapy: Approaches in Early-Stage NSCLC

Written by Emma Hitt Nichols, PhD

Stereotactic body radiation therapy (SBRT) is effective in patients with early-stage non-small cell lung cancer (NSCLC) who are either medically inoperable or high-risk operable. Krzysztof Konopa, MD, Medical University of Gdańsk, Gdańsk, Poland, discussed treatment approaches and considerations for the use of SBRT in this population.

The standard of care for patients with early-stage NSCLC is surgical resection; however, more than 20% of patients cannot undergo surgery due to comorbidities, and 30% of patients do not undergo surgery in the United States [Cykert S et al. *JAMA* 2010].

SBRT is effective in patients with medically inoperable NSCLC. In a Phase 2 trial of patients with inoperable NSCLC, the 3-year estimated overall survival (OS) rate was 59.5%, and the lung cancer-specific survival rate was 88.4% [Baumann P et al. *J Clin Oncol* 2009]. In the Radiation Therapy Oncology Group (RTOG) 0236 Phase 2 trial of patients with inoperable NSCLC, OS was more than 50% and disease-free survival (DFS) was about 50% [Timmerman R et al. *JAMA* 2010]. Similarly, in the medically inoperable arm of the Japan Clinical Oncology Group (JCOG) 0403 Phase 2 trial, the 3-year OS rate was 59.9% (95% confidence interval [CI], 51.4% to 67.5%), and the 3-year local control rate was 88% [Nagata Y et al. *Int J Radiat Oncol Biol Phys* 2012].

SBRT may also be effective in patients who have early-stage NSCLC and are at high risk for surgery. In a retrospective study comparing SBRT to wedge resection, OS was greater in patients who underwent

wedge resection, whereas SBRT resulted in better local control and freedom from failure [Grills IS et al. *J Clin Oncol* 2010]. In a population-based matched-pair comparison, OS was greater in patients who received SBRT until about 24 months; OS was greater at 36 months in patients who underwent resection [Palma D et al. *Radiother Oncol* 2011]. In another retrospective study, SBRT resulted in improved OS compared with surgery, but regional control and cancer-specific survival were similar among both arms [Robinson CG et al. *J Thorac Oncol* 2013]. A Surveillance, Epidemiology, and End Results (SEER)-Medicare retrospective analysis found that the rate of OS was greatest in patients who underwent lobectomy, followed by sublobar resection, SBRT, conventional radiation, and no treatment [Shrivani SM et al. *Int J Radiat Oncol Biol Phys* 2012].

Prof. Konopa stated these data indicate that the efficacy of SBRT is consistent among studies, with 3-year rates of tumor control of 85% to 90%, rates of OS of 50% to 60% in medically inoperable patients, and 76% for high-risk operable patients.

Patients with large NSCLC tumors also benefit from SBRT. In a retrospective analysis, patients with stage T2 to T4 NSCLC with a planned target volume (PTV) of ≤ 106 demonstrated a significant increase in local failure-free survival compared with patients with a PTV > 106 (log-rank $p=0.05$). However, there is a risk of symptomatic pneumonitis, particularly in patients with an internal target volume (ITV) of ≥ 145 cc, and those who receive a contralateral mean lung dose of ≥ 3.6 Gy [Bongers EM et al. *Radiother Oncol* 2013]. Dr. Konopa stated that although SBRT for large tumors appears to be effective for local control, there is still a risk of distant failures and symptomatic pneumonitis. Therefore, additional studies are needed to determine if SBRT is beneficial in this population.

Prof. Konopa stated he thinks the data suggest that SBRT should be standard therapy for medically inoperable NSCLC, and it is comparable to surgery in patients with early-stage NSCLC who are considered at high risk for surgery, such as elderly patients.



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