NEWSBRIEFING 2

5 Stereotactic Body Radiation Therapy for Medically Inoperable Early Stage Lung Cancer Patients: Analysis of RTOG 0236

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Purpose/Objective(s): The Radiation Therapy Oncology Group (RTOG) protocol RTOG 0236 was a phase II trial utilizing stereotactic body radiation therapy (SBRT) with ablative prescription dose to treat early stage medically inoperable non-small cell lung cancer patients (pts).
Materials/Methods: All pts were required to have documented baseline medical conditions precluding lobectomy. Pts with biopsy proven peripheral (greater than 2 cm from the central bronchial tree) T1-T3, N0, M0 tumors were eligible. The prescription dose was 20 Gy per fraction times 3 fractions (60 Gy total dose) assuming all water density. Subsequent analysis with proper tissue heterogeneity correction showed the actual dose to be approximately 54 Gy total. The treatment was delivered in 1½-2 weeks. Rigorous central accreditation and quality assurance assessments were used to assure pts were treated according to protocol guidelines. The primary endpoint was two-year local control with overall and disease free survival, toxicity, regional failure and disseminated failure as secondary endpoints. Local failure was defined as enlargement of at least 20% on CT and either biopsy confirming cancer or PET uptake similar to the patient's pretreatment imaging. Marginal failures (within 1 cm of the treated lesion) were considered local failures for analysis.
Results: The study opened May 2004 and closed October 2006 after accruing a total of 59 pts. Of 55 evaluable pts, 44 had T1 and 11 had T2 tumors. Median age was 72 years. Contouring compliance indicated 98% of targets and 73% of normal tissue structures were outlined per protocol or with only minor deviations. Protocol related grade 3 and 4 adverse events were reported in thirteen (24%) and 2 (4%) patients, respectively. The most common severe adverse event categories were pulmonary/upper respiratory and musculoskeletal. No treatment related deaths have been reported. With median follow-up of 24.8 months, 3 patients (5%) have been scored with a local failure giving an estimated 2-year local control rate of 93.7% (95% CI: 81.5%, 98.0%). No patients have experienced regional failure while eight patients (15%) experienced distant failure. Two year estimates of disease free and overall survival are 66.6% (95% CI: 52.2%, 77.5%) and 72.0% (95% CI: 57.9%, 82.1%), respectively.
Conclusions: SBRT using a total (heterogeneity corrected) dose of 54 Gy in 3 fractions appears to be associated with very high rates of local tumor control and moderate treatment related morbidity in a population of medically inoperable early stage non-small cell lung cancer patients with peripheral lesions. Two year disease free and overall survival is encouraging for this frail population.

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