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A Multicenter Phase II Study of Stereotactic Body Radiation Therapy for Hepatocellular Carcinoma

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Purpose/Objective(s): To evaluate the toxicity and treatment outcomes of stereotactic body radiation therapy (SBRT) for hepatocellular carcinoma (HCC).

Materials/Methods: A total of 73 patients with unresectable HCC showing an incomplete response after 1-5 sessions of transarterial chemoembolization were enrolled in a phase II clinical trial of SBRT from 6 institutions between January 2012 and April 2015. SBRT was delivered with a total dose of 45-60 Gy in 3 fractions within 14 days, with ≥48 hour intervals between each fraction. The treatment response was evaluated using the Modified Response Evaluation Criteria in Solid Tumors (mRECIST). Toxicity was graded using the National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0. Radiation-induced liver disease (RILD) was analyzed. Survival outcomes were analyzed with the Kaplan-Meier method. This trial is registered with Clinical Trials.gov, number NCT01850667.

Results: Sixty-seven patients were evaluable with a median follow-up of 19 months (range, 2-42 months). Local control rate at 2 years and 3 years was 94.0% (95% confidence interval [CI], 76.1%-98.6%) and 89.0% (95% CI, 67.8%-96.6%), respectively. Overall survival rate at 2 years and 3 years was 83.5% (95% CI, 68.5%-91.7%) and 75.1% (95% CI, 50.9%-88.6%), respectively. Progression-free survival rate at 2 years and 3 years was 47.2% (95% CI, 32.8%-60.4%) and 37.2% (95% CI, 21.1%-53.3%), respectively. Intrahepatic failure-free survival rate at 2 years and 3 years was 51.1% (95% CI, 36.8%-63.8%) and 41.3% (95% CI, 24.9%-57.0%), respectively. Extrahepatic failure-free survival rate at 2 years and 3 years was 96.7% (95% CI, 87.3%-99.2%) and 87.0% (95% CI, 52.8%-97.0%), respectively. Severe treatment-related toxicities were reported in 2 patients (3.2%). One patient developed non-classic RILD at 4 months. Long-term toxicity of grade 3 esophageal ulcer with stenosis was reported in 1 patient at 6 months.

Conclusion: This is the first multicenter phase II study for SBRT in HCC. This treatment regimen is feasible and effective as evidenced by the high rates of tumor control, overall survival, and acceptable treatment-related toxicity. These results warrant confirmation in a randomized trial.

LBA-10

NRG Oncology/RTOG 1014: 3 Year Efficacy Report From a Phase II Study of Repeat Breast Preserving Surgery and 3D Conformal Partial Breast Re-Irradiation (PBrI) for In-Breast Recurrence

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Purpose/Objective(s): RTOG 1014 is a prospective phase II trial of 3D-conformal external beam PBrI following repeat lumpectomy for in-breast recurrence following previous whole breast irradiation (WBI). The primary endpoint was to evaluate skin, breast, and chest wall adverse events occurring within 1 year from treatment and has been previously reported. Initial efficacy data and treatment-related adverse events (AE) > 1 year are reported.

Materials/Methods: Eligibility criteria included in-breast recurrence occurring >1 year (yr) following WBI for initial lesion and confirmed to be <3cm, unifocal, and resected with negative margins. Axilla was documented to be pathologic N0 or N1 without extracapsular extension. PBrI was targeted to surgical cavity + 1.5 cm for clinical target volume and an additional 1 cm expansion. Prescription dose of 45 Gy was delivered 1.5Gy BID for 30 treatments with 3-dimensional conformal radiotherapy (3DCRT). Secondary objectives include late adverse events (AEs) (> 1 yr from the end of PBrI), as graded by CTCAE version 4.0, and efficacy endpoints. In-breast recurrence (IBR) and freedom from mastectomy (MF) were estimated using the cumulative incidence method. Distant metastasis-free survival (DMFS) and overall survival (OS) rates were estimated using the Kaplan-Meier method.

Results: Between 2010 and 2013, 65 pts were accrued and 58 eligible, completed treatment, and evaluable for efficacy. Median age is 67.5 yo. 23 pts were DCIS and 35 invasive; 20 ≤1cm; 14 >1 to ≤2cm; and 1 >2cm. All pts were node negative. Systemic therapy was delivered in 51.7%. Estrogen receptor is positive in 75.9%, progesterone receptor positive in 56.9%, and Her2 positive in 17%. Median follow-up is 3.64 yr. There have been 4 patients (6.9%) with reported late grade 3 treatment-related AEs; no grade ≥4 AEs. There have been 2 patients who had an IBR for a 3-yr estimate of 3.7%; 4 patients had an ipsilateral mastectomy for a second breast conservation 3-yr estimate of 94.8%. Both DMFS and OS had a 3-yr estimate of 94.8%. Of the 2 IBRs, 1 was located within and 1 outside the treatment field. There were 4 ipsilateral mastectomies, 2 for IBR, and 1 for toxicity. There was 1 bilateral mastectomy for contralateral disease.

Conclusion: Initial treatment outcome for partial breast re-irradiation with 3DCRT following second lumpectomy for patients experiencing in-breast failures after WBI demonstrates a successful second breast conservation and high local control. This adds to the growing data supporting this treatment approach as an alternative to mastectomy.

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The *KRAS*-variant is a Biomarker of Cetuximab Response and Altered Immunity in Head and Neck Cancer: NRG Oncology/RTOG 0522

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