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Abstract

Interim Analysis of a Phase II Randomized Single Blind Trial of Hypofractionated Stereotactic Radiation for Recurrent GBM

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Abstract

Objectives: The ideal regimen for reirradiating GBM remains to be determined. We report an interim analysis of a prospective randomized phase II trial comparing two different dose regimens of Hypofractionated Stereotactic Radiation Therapy (HSFRT) to treat recurrent GBM. We hypothesized that a higher dose could have better tumor control with acceptable complication rates.

Methods: Patients with recurrent GBM, KPS > 60 with at least 5 months interval from the end of first radiation therapy were randomly assigned to receive HSFRT in either 35Gy in 5 fractions or 25Gy in 5 fractions. Treatment was delivered every other day during weekdays. Primary endpoint was Progression Free-Survival (PFS). Secondary endpoints were Overall Survival (OS) and Toxicity. We report an interim analysis after 24 patients were enrolled. This trial is registered at Clinical Trials.gov: NCT01464177.

Results: From October 2011 to July 2015, 22 out of 24 patients received at least one fraction of radiation and were analyzed. Median age was 50 years, with a median KPS of 70. Before reirradiation, surgery was performed in 68% of patients, with a near total resection in 41% of patients. Median GTV size was 57cc. With a median follow-up for patients alive of 24.7 months, median PFS was 7.5 months in the 5x5Gy group and 9.4 months in the 5x7Gy group (p= 0.97). Median OS was 9.2 months in the 5x5Gy group and 10.8 months in the 5x7Gy (p=0.89). Treatment was well tolerated in both groups. There was one grade 1 radiation necrosis in the 5x5Gy group and three grade 3 in the 5x7Gy group.

Conclusions: In this interim analysis, we have found no difference in PFS or OS between the two fractionations. HFSRT seems feasible with acceptable toxicity. Our data is not definitive and we plan to continue accrual for this trial.

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