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## A phase I dose-escalation study of fractionated stereotactic radiosurgery in combination with gefitinib in patients with recurrent malignant gliomas.

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### Abstract

**PURPOSE:** To determine the maximum tolerated dose (MTD) of fractionated stereotactic radiosurgery (SRS) with gefitinib in patients with recurrent malignant gliomas.

**METHODS AND MATERIALS:** A Phase I clinical trial was performed. Eligible patients had pathologically proved recurrent anaplastic astrocytoma or glioblastoma. Patients started gefitinib (250 mg/day) 7 days before SRS and continued for 1 year or until disease progression. SRS was delivered in three fractions over 3 days. The planning target volume (PTV) was the T1-weighted MRI postcontrast enhancing lesion+2 mm. The first cohort received an SRS dose of 18 Gy, and subsequent cohorts received higher doses up to the maximum dose of 36 Gy. Dose-limiting toxicity (DLT) was any Grade 3 toxicity. The MTD was exceeded if 2 of 6 patients in a cohort experienced DLT.

**RESULTS:** Characteristics of the 15 patients enrolled were: 9 men, 6 women; median age, 47 years (range, 23-65 years); 11 glioblastoma, 4 AA; median prior RT dose, 60 Gy (range, 54-61.2 Gy); median interval since RT, 12 months (range, 3-57 months); median PTV, 41 cc (range, 12-151 cc). Median follow-up time was 7 months (range, 2-28 months). Median time on gefitinib was 5 months (range, 2-12 months). No patient experienced a DLT, and the SRS dose was escalated from 18 to 36 Gy. Grade 1-2 gefitinib-related dermatitis and diarrhea were common (10 and 7 patients, respectively).

**CONCLUSION:** Fractionated SRS to a dose of 36 Gy in three fractions is well tolerated with gefitinib at daily dose of 250 mg. Further studies of SRS and novel molecular targeted agents are warranted in this challenging clinical setting.

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