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A phase I dose escalation study of hypofractionated stereotactic radiotherapy as salvage therapy for persistent or recurrent malignant glioma.

Hudes RS, Corn BW, Werner-Wasik M, Andrews D, Rosenstock J, Thoron L, Downes B, Curran WJ Jr.

Department of Radiation Oncology, Wills Eye Hospital, Kimmel Cancer Center, Jefferson Medical College of Thomas Jefferson University, Philadelphia, PA 19107, USA.

Abstract

PURPOSE: A phase I dose escalation of hypofractionated stereotactic radiotherapy (H-SRT) in recurrent or persistent malignant gliomas as a means of increasing the biologically effective dose and decreasing the high rate of reoperation due to toxicity associated with single-fraction stereotactic radiosurgery (SRS) and brachytherapy.

MATERIALS AND METHODS: From November 1994 to September 1996, 25 lesions in 20 patients with clinical and/or imaging evidence of malignant glioma persistence or recurrence received salvage H-SRT. Nineteen patients at the time of initial diagnosis had glioblastoma multiforme (GBM) and one patient had an anaplastic astrocytoma. All of these patients with tumor persistence or recurrence had received initial fractionated radiation therapy (RT) with a mean and median dose of 60 Gy (44.0-72.0 Gy). The median time from completion of initial RT to H-SRT was 3.1 months (0.7-45.5 months). Salvage H-SRT was delivered using daily 3.0-3.5 Gy fractions (fxs). Three different total dose levels were sequentially evaluated: 24.0 Gy/3.0 Gy fxs (five lesions), 30.0 Gy/3.0 Gy fxs (10 lesions), and 35.0 Gy/3.5 Gy fxs (nine lesions). Median treated tumor volume measured 12.66 cc (0.89-47.5 cc). The median ratio of prescription volume to tumor volume was 2.8 (1.4-5.0). Toxicity was judged by RTOG criteria. Response was determined by clinical neurologic improvement, a decrease in steroid dose without clinical deterioration, and/or radiologic imaging.

RESULTS: No grade 3 toxicities were observed and no reoperation due to toxicity was required. At the time of analysis, 13 of 20 patients had died. The median survival time from the completion of H-SRT is 10.5 months with a 1-year survival rate of 20%. Neurological improvement was found in 45% of patients. Decreased steroid requirements occurred in 60% of patients. Minor imaging response was noted in 22% of patients. Using Fisher's exact test, response of any kind correlated strongly to total dose ($p = 0.0056$). None of six lesions treated with 21 Gy or 24 Gy responded, whereas there was a 79% response rate among the 19 lesions treated with 30 or 35 Gy. Tumor volumes $<$ or $=$ 20 cc were associated with a higher likelihood of response ($p = 0.053$).

CONCLUSIONS: H-SRT used in this cohort of previously irradiated patients with malignant glioma was not associated with the need for reoperation due to toxicity or grade 3 toxicity. This low toxicity profile and encouraging H-SRT dose-related response outcome justifies further evaluation and dose escalation.

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