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Prolonged survival for patients with newly diagnosed, inoperable glioblastoma with 3-times daily ultrafractionated radiation therapy.

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Abstract

Ultrafractionation of radiation therapy is a novel regimen consisting of irradiating tumors several times daily, delivering low doses (<0.75 Gy) at which hyperradiosensitivity occurs. We recently demonstrated the high efficiency of ultrafractionated radiotherapy (RT) on glioma xenografts and report here on a phase II clinical trial to determine the safety, tolerability, and efficacy of an ultrafractionation regimen in patients with newly and inoperable glioblastoma (GBM). Thirty-one patients with histologically proven, newly diagnosed, and unresectable supratentorial GBM (WHO grade IV) were enrolled. Three daily doses of 0.75 Gy were delivered at least 4 hours apart, 5 days per week over 6-7 consecutive weeks (90 fractions for a total of 67.5 Gy). Conformal irradiation included the tumor bulk with a margin of 2.5 cm. The primary end points were safety, toxicity, and tolerability, and the secondary end points were overall survival (OS) and progression-free survival (PFS). Multivariate analysis was used to compare the OS and PFS with the EORTC-NCIC trial 26981-22981/CE.3 of RT alone vs radiation therapy and temozolomide (TMZ). The ultrafractionation radiation regimen was safe and well tolerated. No acute Grade III and/or IV CNS toxicity was observed. Median PFS and OS from initial diagnosis were 5.1 and 9.5 months, respectively. When comparing with the EORTC/NCIC trial, in both PFS and OS multivariate analysis, ultrafractionation showed superiority over RT alone, but not over RT and TMZ. The ultrafractionation regimen is safe and may prolong the survival of patients with GBM. Further investigation is warranted and a trial associating ultrafractionation and TMZ is ongoing.

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