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Progression-free survival: an important end point in evaluating therapy for recurrent high-grade gliomas.

Lamborn KR, Yung WK, Chang SM, Wen PY, Cloughesy TF, DeAngelis LM, Robins HI, Lieberman FS, Fine HA, Fink KL, Junck L, Abrey L, Gilbert MR, Mehta M, Kuhn JG, Aldape KD, Hibberts J, Peterson PM, Prados MD; North American Brain Tumor Consortium.

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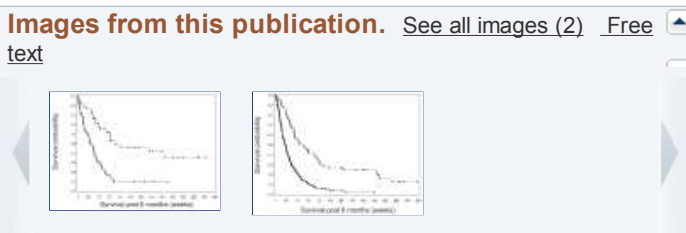
Abstract

The North American Brain Tumor Consortium (NABTC) uses 6-month progression-free survival (6moPFS) as the efficacy end point of therapy trials for adult patients with recurrent high-grade gliomas. In this study, we investigated whether progression status at 6 months predicts survival from that time, implying the potential for prolonged survival if progression could be delayed. We also evaluated earlier time points to determine whether the time of progression assessment alters the strength of the prediction. Data were from 596 patient enrollments (159 with grade III gliomas and 437 with grade IV tumors) in NABTC phase II protocols between February 1998 and December 2002. Outcome was assessed statistically using Kaplan-Meier curves and Cox proportional hazards models. Median survivals were 39 and 30 weeks for patients with grade III and grade IV tumors, respectively. Twenty-eight percent of patients with grade III and 16% of patients with grade IV tumors had progression-free survival of >26 weeks. Progression status at 9, 18, and 26 weeks predicted survival from those times for patients with grade III or grade IV tumors ($p < 0.001$ and hazard ratios < 0.5 in all cases). Including KPS, age, number of prior chemotherapies, and response in a multivariate model did not substantively change the results. Progression status at 6 months is a strong predictor of survival, and 6moPFS is a valid end point for trials of therapy for recurrent malignant glioma. Earlier assessments of progression status also predicted survival and may be incorporated in the design of future clinical trials.

Comment in

[Neuro Oncol.](#) 2008 Dec;10(6):1171-2.

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