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Six-month progression-free survival as an alternative primary efficacy endpoint to overall survival in newly diagnosed glioblastoma patients receiving temozolomide.

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We assessed six-month progression-free survival (PFS) as an alternative primary efficacy endpoint to overall survival in newly diagnosed glioblastoma multiforme (GBM) patients receiving temozolomide (TMZ). A total of 183 patients with newly diagnosed GBM enrolled in 3 phase II protocols at the University of California-San Francisco were included. Patients were treated with interventions based on the Stupp regimen, each with the added component of a second oral agent given concurrently with radiotherapy and TMZ, followed by its coadministration with adjuvant TMZ. We examined whether progression status at 2, 4, and 6 months predicted subsequent survival using the landmark analysis. The hazard ratios of death as a function of progression status were estimated based on the Cox proportional hazards model after adjustment for putative prognostic factors. Progression status at 2, 4, and 6 months were all consistently found to be strong predictors of subsequent survival in all studies. The study-specific hazard ratios associated with progression status at 6 months ranged from 2.03 to 3.39. The hazard ratios associated with the earlier time points (2- and 4-month progression) all exceeded 2 in magnitude, ranging from 2.29 to 4.73. P-values were statistically significant for all time points. In this report, we demonstrated a strong association between the endpoints of PFS at 2, 4, and 6 months and survival. Patients who showed the signs of early progression were at significantly higher risk of earlier death. Our analysis suggests that 6-month PFS may be an appropriate primary endpoint in the context of phase II upfront GBM trials in the TMZ era.

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