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Abstract

PURPOSE: Radiation Therapy Oncology Group trial 0525 tested whether dose-intensifying temozolomide versus standard chemoradiotherapy improves overall survival (OS) or progression-free survival (PFS) in newly diagnosed glioblastoma. Tests of neurocognitive function (NCF) and symptoms (using the MD Anderson Symptom Inventory-Brain Tumor module; MDASI-BT) and of quality of life (European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire [EORTC QLQ]-C30/BN20) examined the net clinical benefit (NCB) of therapy.

PATIENTS AND METHODS: NCF tests (Hopkins Verbal Learning Test-Revised, Trail Making Test, and Controlled Oral Word Association), MDASI-BT, and EORTC QLQ-C30/BN20 were completed in a subset of patients. Multivariate Cox proportional hazard regression modeling determined the prognostic value of baseline and early change from baseline to cycle 1 for OS and PFS. Two-sample proportional test statistic was used to evaluate differences between treatments (dose-dense vs standard-dose) on NCB measures from baseline to cycle 4 in stable patients.

RESULTS: Overall, 182 patients participated in the study. Baseline NCF tests and the physical functioning quality of life scale were associated with OS and PFS. Baseline to cycle 1 in all NCB components were associated with OS and PFS. There was greater deterioration in the dose-dense arm from baseline to cycle 4 in the Global Health and Motor Function subscales (EORTC QLQ-C30/BN20) as well as in overall symptom burden, overall symptom interference, and activity-related symptom interference subscales (MDASI-BT). There were no between-arm differences in NCF.

CONCLUSION: Longitudinal collection of NCB measures is feasible in cooperative group studies and provides an added dimension to standard outcome measures. Greater adverse symptom burden and functional interference, as well as decreased global health and motor function were observed in patients randomly assigned to the dose-dense arm. Baseline and early change in NCB measures were associated with decreased rates of survival.

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