The impact of enrollment in clinical trials on survival of patients with glioblastoma.


Department of Neurosurgery, Tel Aviv Medical Center, 6 Weizman Street, Tel Aviv 64239, Israel.

Abstract

The impact of enrollment in a clinical study on the survival of patients with glioblastoma has not been established. We retrospectively analyzed 564 patients with newly diagnosed glioblastoma treated between 1995 and 2008. They were divided into those enrolled in a clinical trial and randomized to a treatment or control arm, and those not enrolled and who received best standard of care (BSC). The three groups were matched for age and Karnofsky performance scale (KPS) score at presentation, and included only patients who underwent at least one tumor resection. Survival analysis was performed and multivariate Cox proportional hazards model and recursive partitioning analysis (RPA) identified predictors of survival. Following the matching process, 261 patients remained to form the final cohort. Of the 124 patients enrolled in a study, 81 (31.0%) were randomized to the treatment and 43 (16.5%) to the control arms. The overall median survival for the BSC (n=137), control, and treatment groups was 11.57 months (95% confidence interval [CI], 10.41-12.73), 16.27 months (95% CI, 14.10-18.43) and 16.10 months (95% CI, 14.34-17.86), respectively (p=0.002). Participation in a clinical trial, regardless of the arm, was a significant predictor of survival, as were age and KPS at diagnosis. The RPA also demonstrated a favorable impact of participation in a clinical trial. Additional tumor resections and various treatment modalities were administered with significantly higher frequency among patients enrolled in clinical studies. Thus, enrollment in a clinical study carried a significant survival advantage for patients with glioblastoma, raising practical and ethical issues regarding the quality of care of patients who receive "standard" therapy.