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## A North American brain tumor consortium (NABTC 99-04) phase II trial of temozolomide plus thalidomide for recurrent glioblastoma multiforme.

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### Abstract

**BACKGROUND:** Laboratory and clinical data suggest that the anti-angiogenic agent, thalidomide, if combined with cytotoxic agents, may be effective against recurrent glioblastoma multiforme (GBM).

**OBJECTIVES:** To determine 6-month progression-free survival (6PFS) and toxicity of temozolomide plus thalidomide in adults with recurrent GBM.

**PATIENTS AND METHODS:** Eligible patients had recurrent GBM after surgery, radiotherapy, and/or adjuvant chemotherapy. Temozolomide was given at 150-200 mg/m<sup>2</sup>/day on days 1-5 of each 28-day cycle. Thalidomide was given orally at 400 mg at bedtime (days 1-28) and increased to 1,200 mg as tolerated. Patients were evaluated with magnetic resonance imaging scans every 56 days. The study was designed to detect an increase of the historical 6PFS for GBM from 10 to 30%.

**RESULTS:** Forty-four patients were enrolled, 43 were evaluable for efficacy and safety. The study population included 15 women, 29 men; median age was 53 years (range 32-84); median Karnofsky performance status was 80% (range 60-100%). Thirty-six (82%) patients were chemotherapy-naïve. There were 57 reports of toxicity of grade 3 or greater. Non-fatal grade 3-4 granulocytopenia occurred in 15 patients (34%). The objective response rate was 7%. The estimated probability of being progression-free at 6 months with this therapy is 24% [95% confidence interval (C.I.) 12-38%]. The median time to progression is 15 weeks (95% C.I. 10-20 weeks). There was no observed correlation between serum levels of vascular endothelial growth factor, basic fibroblast growth factor, and IL-8 and the 6PFS outcome.

**CONCLUSION:** This drug combination was reasonably safe, but with little indication of improvement compared to temozolomide alone.

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