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Phase II study of carboplatin, irinotecan, and bevacizumab for bevacizumab naïve, recurrent glioblastoma.

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Abstract

We evaluated the efficacy of carboplatin, irinotecan, and bevacizumab among bevacizumab-naïve, recurrent glioblastoma (GBM) patients in a phase 2, open-label, single arm trial. Forty eligible patients received carboplatin (area under the plasma curve [AUC] 4 mg/ml-min) on day one, while bevacizumab (10 mg/kg) and irinotecan (340 mg/m²) for patients on CYP3A-enzyme-inducing anti-epileptics [EIAEDs] and 125 mg/m²) for patients not on EIAEDs) were administered on days 1 and 14 of every 28-day cycle. Patients were evaluated after each of the first two cycles and then after every other cycle. Treatment continued until progressive disease, unacceptable toxicity, non-compliance, or voluntary withdrawal. The primary endpoint was progression-free survival at 6 months (PFS-6) and secondary endpoints included safety and median overall survival (OS). All patients had progression after standard therapy. The median age was 51 years. Sixteen patients (40%) had a KPS of 90-100, while 27 (68%) were at first progression. The median time from original diagnosis was 11.4 months. The PFS-6 rate was 46.5% (95% CI: 30.4, 61.0%) and the median OS was 8.3 months [95% confidence interval (CI): 5.9, and 10.7 months]. Grade 4 events were primarily hematologic and included neutropenia and thrombocytopenia in 20 and 10%, respectively. The most common grade 3 events were neutropenia, thrombocytopenia, fatigue, and infection in 25, 20, 13, and 10%, respectively. Eleven patients (28%) discontinued study therapy due to toxicity and 17 patients (43%) required dose modification. One patient died due to treatment-related intestinal perforation. The addition of carboplatin and irinotecan to bevacizumab significantly increases toxicity but does not improve anti-tumor activity to that achieved historically with single-agent bevacizumab among bevacizumab-naïve, recurrent GBM patients. (ClinicalTrials.gov number NCT00953121).

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