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Phase 2 trial of irinotecan and thalidomide in adults with recurrent anaplastic glioma.

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Abstract

BACKGROUND: Therapeutic options for patients with anaplastic gliomas (AGs) are limited despite better insights into glioma biology. The authors previously reported improved outcome in patients with recurrent glioblastoma treated with thalidomide and irinotecan compared with historical controls. Here, results of the AG arm of the study are reported, using this drug combination.

METHODS: Adults with recurrent AG previously treated with radiation therapy, with Karnofsky performance score ≥ 70 , adequate organ function and not on enzyme-inducing anticonvulsants were enrolled. Treatment was in 6-week cycles with irinotecan at 125 mg/m² weekly for 4 weeks followed by 2 weeks off, and thalidomide at 100 mg daily increased to 400 mg/day as tolerated. The primary endpoint was progression-free survival rate at 6 months (PFS-6), and the secondary endpoints were overall survival (OS) and response rate (RR).

RESULTS: In 39 eligible patients, PFS-6 for the intent-to-treat population was 36% (95% confidence interval [CI] = 21%, 53%), median PFS was 13 weeks (95% CI = 6%, 28%) and RR was 10% (95% CI = 3%, 24%). Radiological findings included 2 complete and 2 partial responses and 17 stable disease. Median OS from study registration was 62 weeks, (95% CI = 51, 144). Treatment-related toxicities (grade 3 or higher) included neutropenia, diarrhea, nausea, and fatigue; 6 patients experienced venous thromboembolism. Four deaths were attributable to treatment-related toxicities: 1 from pulmonary embolism, 2 from colitis, and 1 from urosepsis.

CONCLUSIONS: The combination of thalidomide and irinotecan did not achieve sufficient efficacy to warrant further investigation against AG, although a subset of patients experienced prolonged PFS/OS. A trial of the more potent thalidomide analogue, lenalidomide, in combination with irinotecan against AG is currently ongoing. Cancer 2011;. © 2011 American Cancer Society.

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