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Phase II study of temozolomide and thalidomide with radiation therapy for newly diagnosed glioblastoma multiforme.

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Abstract

PURPOSE: The chemotherapeutic agent temozolomide (TMZ) and the antiangiogenic agent thalidomide have both demonstrated antitumor activity in patients with recurrent malignant glioma. The objectives of this study were to determine if the combined strategy of these oral agents with radiation therapy (RT) is associated with an improved median survival of patients with newly diagnosed glioblastoma multiforme and to evaluate toxicity.

METHODS AND MATERIALS: Sixty-seven patients were enrolled in this trial. Radiotherapy parameters were a total dose of 60 Gy delivered in 2 Gy fractions over 6 weeks. Temozolomide was administered starting the first day of RT at 150 mg/m² daily for 5 days every 4 weeks for the first cycle and escalated to a maximum dose of 200 mg/m². Thalidomide was started on Day 7 of RT at 200 mg and escalated by 100-200 mg every 1-2 weeks depending on patient tolerance, to a maximum of 1,200 mg daily.

RESULTS: Sixty-one patients have progressed, with a median time to progression of 22 weeks. Fifty-six patients have died, and the median survival was 73 weeks.

CONCLUSIONS: This strategy of combination TMZ, thalid and RT was relatively well tolerated with favorable survival outcome for patients with GM when compared to patients not treated with adjuvant chemotherapy and similar to those who have received nitrosourea adjuvant chemotherapy. It is unclear the added advantage thalid has in combination with TMZ for this patient population.

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