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Phase II study of temozolomide, thalidomide, and celecoxib for newly diagnosed glioblastoma in adults.

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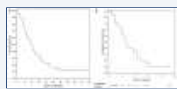
Abstract

We conducted a phase II study of the combination of temozolomide and angiogenesis inhibitors for treating adult patients with newly diagnosed glioblastoma. Patients who had stable disease following standard radiation therapy received temozolomide for 5 days in 28-day cycles, in combination with daily thalidomide and **celecoxib**. Patients were treated until tumor progression or development of unacceptable toxicity. Four-month progression-free survival (PFS) from study enrollment was the primary end point, and overall survival (OS) was the secondary end point. In addition, we sought to correlate response with O(6)-methylguanine-DNA methyltransferase promoter methylation status and serum levels of angiogenic peptides. Fifty patients with glioblastoma were enrolled (18 women, 32 men). Median age was 54 years (range, 29-78) and median KPS score was 90 (range, 70-100). From study enrollment, median PFS was 5.9 months (95% confidence interval [CI]: 4.2-8.0) and 4-month PFS was 63% (95% CI: 46%-75%). Median OS was 12.6 months (95% CI: 8.5-16.4) and 1-year OS was 47%. Of the 47 patients evaluable for best response, none had a complete response, five (11%) had partial response, four (9%) had minor response, 22 (47%) had stable disease, and 16 (34%) had progressive disease. Analysis of serial serum samples obtained from 47 patients for four angiogenic peptides failed to show a significant correlation with response or survival for three of the peptides; higher vascular endothelial growth factor levels showed a trend toward correlation with decreased OS ($p=0.07$) and PFS ($p=0.09$). The addition of **celecoxib** and thalidomide to adjuvant temozolomide was well tolerated but did not meet the primary end point of improvement of 4-month PFS from study enrollment.

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