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A phase II trial of thalidomide and procarbazine in adult patients with recurrent or progressive malignant gliomas.

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Abstract

Thalidomide and procarbazine have demonstrated single agent activity against malignant gliomas (MG). We evaluated the combination of thalidomide and procarbazine with a single arm phase II trial in adults with recurrent or progressive MG. Procarbazine was given at a dose of 250 mg/m²/d × 5day q 28 days. Thalidomide was administered at a dose of 200 mg/day continuously. Inpatient dose escalation of thalidomide was attempted (increase by 100 mg/day weekly as tolerated) to a maximum of 800 mg/day. The primary outcome was tumor response, assessed by MRI and CT. Secondary outcomes were progression free survival (PFS), overall survival (OS) and toxicity. In addition, quality of life questionnaires were performed at baseline and prior to each odd cycle in all treated patients. Eighteen patients (median age of 50) were accrued and received a total of 36 cycles (median 2) of therapy. The median maximum thalidomide dose achieved was 400 mg (range 0-800). No complete or partial responses were seen. One patient (6%) experienced stable disease, fourteen (78%) progressed as best response and three (17%) were not evaluable for response. Median time to progression was 2.1 months (95% CI, 1.5-2.5). Seventeen patients have died (one patient lost to follow-up after progression); median survival from enrollment was 7.6 months (95% CI, 3.5-9.4). Grade 3/4 drug related toxicity was minimal. Quality of life diminished over time. The combination of thalidomide and procarbazine demonstrated no efficacy in this trial.

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