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**Phase II trial of temozolomide (TMZ) plus irinotecan (CPT-11) in adults with newly diagnosed glioblastoma multiforme before radiotherapy.**

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This phase II trial evaluated efficacy and safety of temozolomide (TMZ) in combination with irinotecan (CPT-11) before radiotherapy in patients with newly diagnosed glioblastoma multiforme (GBM). Prior to radiotherapy, patients were treated with a maximum of three 6-week cycles of TMZ and CPT-11. Patients received TMZ at a dose of 200 mg/m<sup>2</sup>/day on days 1-5 and CPT-11 on days 1, 8, 22, and 29, with a dose adjustment for enzyme-inducing antiepileptic drug use. The primary end point was objective response rate (ORR). Secondary end points included progression-free survival (PFS), overall survival (OS), safety, and tumor O(6)-methylguanine-DNA methyltransferase (MGMT) expression. Of the 42 patients treated, 8 (19%) patients achieved a partial response. Median PFS and median OS were 3.1 and 13.8 months, respectively. Grade 3 or 4 AEs were documented in 36% of patients, most of which were hematologic (29%). Twenty-four percent of patients had grade 3 or 4 non-hematologic AEs, with gastrointestinal AEs being the most common (12%). Two patients died, one of intracranial hemorrhage and one of treatment-related renal failure. Low MGMT expression, compared with high MGMT expression, showed no significant difference in ORR (25 vs. 8%), median PFS (14 vs. 5 months) or OS (21 vs. 15 months). Although TMZ plus CPT-11 is at least comparable in efficacy to TMZ alone, this combination appears more toxic and poorly tolerated. The lack of correlation of activity with MGMT expression is intriguing, but needs further evaluation in subsequent trials.

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