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## Second-line chemotherapy with fotemustine in temozolomide-pretreated patients with relapsing glioblastoma: a single institution experience.

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### Abstract

To evaluate efficacy and safety of fotemustine chemotherapy in temozolomide (TMZ) pretreated adults with recurrent glioblastoma multiforme (GBM). Primary endpoint was progression-free survival at 6 months. Twenty-seven patients (median age: 56 years; median Karnofsky performance status at progression: 80) with relapsed glioblastoma multiforme underwent fotemustine as second-line chemotherapy after failure of homogeneous postoperative treatment consisting of conformal radiotherapy (60 Gy in 30 fractions) with concomitant TMZ (75 mg/m<sup>2</sup> per day), followed by six courses of TMZ (150-200 mg/m<sup>2</sup> for 5 days every 28 days). Patients were assigned to Radiation Therapy Oncology Group recursive partitioning analysis classes for gliomas. After MRI-proven tumor relapse or progression, all patients underwent chemotherapy with fotemustine, given intravenously 100 mg/m<sup>2</sup> every week for 3 consecutive weeks (induction phase) and then every 3 weeks (maintenance phase). Adequate liver, renal, and bone marrow functions were required. Toxicity grading was based on the National Cancer Institute's Common Toxicity Criteria (version 2.0). Response to treatment was assessed on MacDonald criteria. According to an intention-to-treat-analysis, data on all enrolled patients were included in statistical analysis. Eight partial responses (29.6%) and five cases of stable disease (18.5%) were observed. Median time to progression was 5.7 months. Progression-free survival at 6 months was 48.15%. Median survival from the beginning of fotemustine chemotherapy was 9.1 months. Median survival from diagnosis of glioblastoma was 21.2 months. Toxicity was manageable and mainly hematological (grade 3 thrombocytopenia: three cases; grade 4 leukopenia: one case). Fotemustine has shown therapeutic efficacy as single-drug second-line chemotherapy in treatment of TMZ pretreated patients.

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