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Clinical Study

Temozolomide in Patients with Glioblastoma at Second Relapse after First Line Nitrosourea-Procarbazine Failure: A Phase II Study

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Key Words

- Brain tumors
- Chemotherapy
- Temozolomide
- Recurrent glioblastoma

Abstract

Objectives: To investigate the efficacy of temozolomide (TMZ) in relationship to progression free survival at 6 months (PFS-6), median time to progression (TTP), response rate and toxicity, a phase II study was conducted in patients with recurrent glioblastoma multiforme (GBM) following surgery plus radiotherapy and a first-line regimen based on nitrosourea, procarbazine and vincristine. **Methods:** Forty-two patients with GBM were administered TMZ at the dose of 150 mg/m²/daily for 5 days every 4 weeks. **Results:** The PFS-6 and at 12 months (PFS-12) was 24% (95% Confidence Interval [CI] = 14-42%) and 8% (CI = 2-27%), respectively, with a median TTP of 11.7 weeks (CI = 9-22 weeks). The response was assessed in all 42 patients; we observed 2 complete responses (CR) (4.7%), 6 partial responses (PR) (14.3%), and 9 stable disease (SD) (21.4%), with CR+PR = 19% (CI = 7-31%). **Conclusion:** TMZ as a second line regimen is a valid option in patients with heavily pretreated GBM.

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