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**Phase II study of temozolomide in heavily pretreated cancer patients with brain metastases.**

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**Source**

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**Abstract**

**PURPOSE:**

To determine the efficacy, tolerability, and safety of temozolomide in heavily pretreated patients with solid tumors and brain metastases.

**PATIENTS AND METHODS:**

Twenty-seven of twenty-eight enrolled patients with brain metastases from solid tumors received temozolomide (150 mg/m<sup>2</sup>/day for five days every 28 days). Twelve patients had non-small-cell lung cancer, five patients had small-cell lung cancer, four patients had breast cancer, and seven patients had other solid tumors. The majority of the patients had multiple metastatic sites, a poor performance status, and had been heavily pretreated. The primary end points were objective response rate, time to progression, and overall survival. Secondary end points included safety and tolerability, and neurologic performance status.

**RESULTS:**

A partial response was achieved in 1 (4%) of 24 evaluable patients. Disease stabilization was observed in four (17%) patients. Overall median survival was 4.5 months and median time to progression was 3 months. Improvements in clinical neurologic status were achieved in 10 (37%) patients. Treatment with temozolomide was well tolerated. Four patients had grade 3 nausea and vomiting. No grade 4 toxicity or treatment-related deaths were observed.

**CONCLUSIONS:**

Temozolomide demonstrated encouraging activity in the treatment of brain metastases in heavily pretreated patients with solid tumors, and was safe and well tolerated.

**Comment in**

- [Neuro-oncology clinical trials: promise and pitfalls](#). [Ann Oncol. 2001]