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◀ previous 15 of 39 next ▶

Pilot trial of the rate of response, safety, and tolerability of temozolomide and oral VP-16 in patients with recurrent or treatment-induced malignant central nervous system tumors

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Abstract

Background

The aim of this study was to determine the response and toxicity of patients with recurrent or treatment-induced brain tumors to TMZ and oral VP-16.

Methods

Eleven patients with recurrent or treatment-induced malignant CNS tumors, including treatment-induced PNET (in 1 patient), brainstem glioma (in 3 patients; 1 with treatment-induced, 2 with recurrence), recurrent anaplastic astrocytoma (in 3 patients), and recurrent glioblastoma (in 4 patients) were evaluated in a pilot study of TMZ and oral VP-16 chemotherapy. All patients received TMZ at 150 mg/m² per day on days 1 to 5 and oral VP-16 at 50 mg/m² per day on days 1 to 12. Cycles were repeated every 28 days.

Results

None experienced major acute toxicity related to TMZ and oral VP-16 during a total of 52 treatment courses. Five (45%) of 11 patients showed a PR to treatment. Among the 11 patients enrolled, 7 patients are alive with disease at a median of 9 months from time of study entry. The 6-month PFS is 45% (95% CI, 40%-74%). The histologic subtype of the tumor, its location, and its maximum response to chemotherapy did not have an impact on the duration of disease control.

Conclusion

This limited pilot study confirms the innocuousness and the activity of the combination of TMZ and oral VP-16 in recurrent malignant brain tumors. This promising activity warrants further investigation of this combination in larger phase II or III studies.

Abbreviations: ALL, acute lymphoblastic leukemia, CBC, complete blood count, CI, confidence interval, CNS, central nervous system, CR, complete response, CSF, cerebrospinal fluid, M, minor response, MR, magnetic resonance, PD, progressive disease, PFS, progression-free survival, PNET, primitive neuroectodermal tumor, PR, partial response, SD, stable disease, TMZ, temozolomide

Keywords: Malignant glioma, Recurrent, Temozolomide, Treatment induced, VP-16

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