

## ABSTRACT

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Continuing maintenance temozolomide therapy beyond 12 cycles confers no clinical benefit over discontinuation at 12 cycles in patients with IDH1/2-wildtype glioblastoma.

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**OBJECTIVE:** The optimal duration of maintenance temozolomide therapy is controversial. We aimed to examine the clinical benefits of continuing temozolomide therapy beyond 12 cycles in patients with glioblastoma.

**METHODS:** We included 41 patients with isocitrate dehydrogenase 1/2-wildtype glioblastoma, who received 12 or more cycles of temozolomide therapy between June 2006 and December 2019. We evaluated the outcome between 16 patients who continued temozolomide therapy beyond 12 cycles up to 24 cycles ( $\geq 13$  cycles group) and 25 patients wherein temozolomide therapy was discontinued at 12 cycles (12 cycles group).

**RESULTS:** The median progression-free survival and survival time after completing 12 cycles (residual progression-free survival and residual overall survival) did not differ between the 12 cycles group and  $\geq 13$  cycles group (residual progression-free survival: 11.3 vs. 9.2 months,  $P = 0.61$ , residual overall survival: 25.7 vs. 30.2 months,  $P = 0.76$ ). Multivariate analysis including temozolomide therapy beyond 12 cycles, age at 12 cycles, Karnofsky performance status at 12 cycles, residual tumor at 12 cycles, maintenance therapy regimen and O-6-methylguanine deoxyribonucleic acid methyltransferase promoter methylation status revealed that extended temozolomide therapy beyond 12 cycles was not correlated with residual progression-free survival and residual overall survival ( $P = 0.80$  and  $P = 0.41$ , respectively) but Karnofsky performance status at 12 cycles  $\geq 80$  was significantly associated with increased residual overall survival ( $P = 0.0012$ ).

**CONCLUSIONS:** Continuing temozolomide beyond 12 cycles confers no clinical benefit over the discontinuation of temozolomide at 12 cycles. Karnofsky performance status at 12 cycles  $\geq 80$  may serve as a novel predictive factor for long-term survival.

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