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NOA-05 phase 2 trial of procarbazine and lomustine therapy in gliomatosis cerebri.

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Abstract

OBJECTIVE: The NOA-05 multicenter trial was performed to analyze the efficacy of primary chemotherapy with procarbazine and lomustine (PC) in patients with gliomatosis cerebri (GC) and to define clinical, imaging, and molecular factors influencing outcome.

METHODS: Thirty-five patients with previously untreated GC were treated with up to six 56-day courses of 110mg/m(2) lomustine on day 1 and 60mg/m(2) procarbazine on days 8 to 21. The primary endpoint was the rate of patients without therapy failure (defined as progressive disease, death from any cause, or termination of PC therapy before the end of course 4) at 8 months after the beginning of PC chemotherapy.

RESULTS: The failure-free survival rate at 8 months was 50.3%. Median progression-free survival was 14 months. At progression, 12 patients received salvage radiotherapy. Median overall survival was 30 months. Multivariate analysis revealed isocitrate dehydrogenase 1 (IDH1) gene mutation (hazard ratio [HR], 0.11; 95% confidence interval [CI], 0.02-0.58) and initial presentation without a bilateral symmetrical infiltration pattern on magnetic resonance imaging (HR 0.07, 95%CI 0.01-0.54) as independent prognostic factors associated with prolonged survival. IDH1 mutation was significantly associated with MGMT promoter methylation and an oligodendroglial tumor component.

INTERPRETATION: PC chemotherapy is effective in GC. With the NOA-05 trial being the first prospective multicenter trial in GC, PC chemotherapy can be regarded as a promising option for the primary therapy of these tumors. *Ann Neurol* 2011;

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