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Temozolomide in combination with BCNU before and after radiotherapy in patients with inoperable newly diagnosed glioblastoma multiforme.

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Abstract

BACKGROUND: The aim of this study was to evaluate the efficacy and safety of carmustine (BCNU) in combination with temozolomide as first-line chemotherapy before and after radiotherapy (RT) in patients with inoperable, newly diagnosed glioblastoma multiforme (GBM).

PATIENTS AND METHODS: Forty patients were treated with BCNU (150 mg/m²) on day 1 and temozolomide (110 mg/m²/day) on days 1 through 5 of each 42-day cycle for up to four cycles prior to conventional RT (2 Gy fractions to a total of 60 Gy). After RT, BCNU + temozolomide was administered for four additional cycles or until progression. The primary end point was response rate; secondary end points included progression-free survival (PFS); overall survival (OS) and safety.

RESULTS: Sixty per cent of patients completed four cycles of neo-adjuvant BCNU + temozolomide. Objective response rate (intention-to-treat) was 42.5% (95% confidence interval 27% to 58%), including two (5%) complete and 15 (37.5%) partial responses. In the eligible population (n=37) the objective response rate was 46%. Nine (24%) patients had stable disease and 14 (35%) had progressive disease. Median PFS and OS were 7.4 and 12.7 months, respectively. Age was the only significant prognostic factor and tumor location (lobar versus multifocal versus corpus callosum) showed a trend. Grade 3-4 toxicities included thrombocytopenia (n=11) and neutropenia (n=7) for both pre- and post-RT chemotherapy. Four patients required platelet transfusions. No patient discontinued treatment because of toxicity.

CONCLUSIONS: The combination of BCNU plus temozolomide as neo-adjuvant therapy in inoperable GBM exhibited promising activity with a good safety profile and warrants further evaluation.

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