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A phase II study of cisplatin and temozolomide in heavily pre-treated patients with temozolomide-refractory high-grade malignant glioma.

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BACKGROUND: There is pre-clinical evidence of synergism between cisplatin and temozolomide due to higher inhibition of O(6)-alkyl-guanine-alkyltransferase (AGAT), an enzyme involved in the mismatch repair system and in the mechanisms of drug resistance to alkylating agents. **PATIENTS AND METHODS:** Heavily pre-treated patients with temozolomide-refractory high-grade malignant glioma received cisplatin at a dose of 75 mg/m² on day 1 and temozolomide at a dose of 150 mg/m² on days 1 to 5 every 21 days until progression or major toxicity. **RESULTS:** Twenty-four patients were enrolled and a total of 96 cycles were delivered (median for each patient=4). Toxicity was manageable and mostly grade 1-2: haematological, gastroenterological (nausea and vomiting) and fatigue. In patients with glioblastoma, an overall response rate of 29.4% was achieved, with no complete response, and with a disease control rate (responses plus stabilizations) of 64.7%. The median time to progression was 3.8 months (95% confidence interval 2.4-6.8), progression-free survival at 6 months was 28% and overall survival was 7.0 months (95% confidence interval 4.8-11.0). **CONCLUSION:** The combination of temozolomide and cisplatin is safe and moderately effective in the treatment of heavily pre-treated patients with relapsed high-grade glioma refractory to single-agent temozolomide.

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