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Temozolomide Versus Procarbazine, Lomustine, and Vincristine in Recurrent High-Grade Glioma.

Brada M, Stenning S, Gabe R, Thompson LC, Levy D, Rampling R, Erridge S, Saran F, Gattamaneni R, Hopkins K, Beall S, Collins VP, Lee SM.

The Institute of Cancer Research and The Royal Marsden National Health Service Foundation Trust, Sutton; Medical Research Council Clinical Trials Unit; University College Hospital and University College London Cancer Institute, London; Weston Park Hospital, Sheffield; University of Glasgow, Beatson West of Scotland Cancer Centre, Glasgow; Western General Hospital, Edinburgh; The Christie Hospital, Manchester; Bristol Haematology and Oncology Centre, Bristol; and Addenbrookes Hospital, Cambridge, United Kingdom.

Abstract

PURPOSE Temozolomide (TMZ) is an alkylating agent licensed for treatment of high-grade glioma (HGG). No prospective comparison with nitrosourea-based chemotherapy exists. We report, to our knowledge, the first randomized trial of procarbazine, lomustine, and vincristine (PCV) versus TMZ in chemotherapy-naive patients with recurrent HGG.

PATIENTS AND METHODS Four hundred forty-seven patients were randomly assigned to PCV (224 patients) or TMZ (sub-random assignment: TMZ-5 [200 mg/m² for 5 days, 112 patients] or TMZ-21 [100 mg/m² for 21 days, 111 patients]) for up to 9 months or until progression. The primary outcomes were survival (PCV v TMZ) and 12-week progression-free survival (PFS; TMZ-5 v TMZ-21). This study is registered as ISRCTN83176944. **Results** Percentages of patients completing 9 months of treatment in the PCV, TMZ-5, and TMZ-21 arms were 17%, 26%, and 13%, respectively. Major toxicity was similar across all three groups. With a median follow-up time of 12 months and 382 deaths, there was no clear survival benefit when comparing PCV with TMZ (hazard ratio [HR], 0.91; 95% CI, 0.74 to 1.11; P = .350). For TMZ-5 versus TMZ-21, 12-week PFS rates were similar (63.6% and 65.7%, respectively; P = .745), but TMZ-5 improved overall PFS (HR, 1.38; 95% CI, 1.05 to 1.82; P = .023), survival (HR, 1.32; 95% CI, 0.99 to 1.75; P = .056), and global quality of life (49% v 19% improved > 10 points at 6 months, respectively; P = .005). **CONCLUSION** Although TMZ (both arms combined) did not show a clear benefit compared with PCV, comparison of the TMZ schedules demonstrated that the 21-day schedule was inferior to the 5-day schedule in this setting. This challenges the current understanding of increasing TMZ dose-intensity by prolonged scheduling.

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