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Phase II Study of Bevacizumab Plus Temozolomide During and After Radiation Therapy for Patients With Newly Diagnosed Glioblastoma Multiforme.

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Abstract

PURPOSE This open-label, prospective, multicenter single-arm phase II study combined bevacizumab (BV) with radiation therapy (RT) and temozolomide (TMZ) for the treatment of newly diagnosed glioblastoma (GBM). The objectives were to determine the efficacy of this treatment combination and the associated toxicity. **PATIENTS AND METHODS** Seventy patients with newly diagnosed GBM were enrolled between August 2006 and November 2008. Patients received standard RT starting within 3 to 6 weeks after surgery with concurrent administration of daily TMZ and biweekly BV. After completion of RT, patients resumed TMZ for 5 days every 4 weeks and continued biweekly BV. MGMT promoter methylation was assessed on patient tumor tissue. A University of California, Los Angeles/Kaiser Permanente Los Angeles (KPLA) control cohort of newly diagnosed patients treated with first-line RT and TMZ who had mostly received BV at recurrence was derived for comparison. **Results** The overall survival (OS) and progression-free survival (PFS) were 19.6 and 13.6 months, respectively, compared to 21.1 and 7.6 months in the University of California, Los Angeles/KPLA control cohort, and 14.6 and 6.9 months in the European Organisation for Research and Treatment of Cancer-National Cancer Institute of Canada cohort. Correlation of MGMT promoter methylation and improved OS and PFS was retained in the study group. Comparative subset analysis showed that poor prognosis patients (recursive partitioning analysis class V/VI) may derive an early benefit from the use of first-line BV. Toxicity attributable to RT/TMZ was similar, and additional toxicities were consistent with those reported in other BV trials. **CONCLUSION** Patients treated with BV and TMZ during and after RT showed improved PFS without improved OS compared to the University of California, Los Angeles/KPLA control group. Additional studies are warranted to determine if BV administered first-line improves survival compared to BV at recurrence.

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