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The Addition of Bevacizumab to Standard Radiation Therapy and Temozolomide Followed by Bevacizumab, Temozolomide and Irinotecan for Newly Diagnosed Glioblastoma.

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Abstract

PURPOSE: To determine if the addition of bevacizumab to radiation therapy and temozolomide, followed by bevacizumab, temozolomide and irinotecan for newly diagnosed glioblastoma patients is safe and effective.

EXPERIMENTAL DESIGN: Seventy five patients with newly diagnosed glioblastoma were enrolled on this phase II trial that investigated the addition of bevacizumab to standard radiation therapy and daily temozolomide followed by the addition of bevacizumab and irinotecan to adjuvant temozolomide. The bevacizumab was given at 10 mg/kg every 14 days beginning a minimum of 4 weeks post-craniotomy. Two weeks after radiation therapy, the patients began 6-12 cycles of 5-day temozolomide with bevacizumab and irinotecan every 14 days. The primary endpoint was the proportion of patients alive 16 months after informed consent.

RESULTS: The therapy had moderate toxicity. Three patients came off study during radiation therapy, one of whom had a grade 2 CNS hemorrhage. Seventy patients started the post-radiation therapy, and 16 (23%) terminated this adjuvant therapy early due to toxicity. The median overall survival was 21.2 months (95% CI 17.2-25.4), and 65% of the patients were alive at 16 months (95% CI: 53.4%, 74.9%). The median progression-free survival was 14.2 months (95% CI 12-16).

CONCLUSIONS: The addition of bevacizumab to standard radiation therapy and temozolomide followed by bevacizumab, irinotecan and temozolomide for the treatment of newly diagnosed glioblastoma has moderate toxicity and may improve efficacy compared with historical controls. The results from phase III trials are required before the role of bevacizumab for newly diagnosed glioblastoma is established.

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