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The Brain Tumor Cooperative Group NIH Trial 87-01: A Randomized Comparison of Surgery, External Radiotherapy, and Carmustine versus Surgery, Interstitial Radiotherapy Boost, External Radiation Therapy, and Carmustine.

Clinical Studies

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Brain Tumor Cooperative Group; Selker, Robert G. M.D.; Shapiro, William R. M.D.; Burger, Peter M.D.; Blackwood, Margaret S. M.S.; Deutsch, Melvin M.D.; Arena, Vincent C. Ph.D.; Van Gilder, John C. M.D.; Wu, Julian M.D.; Malkin, Mark G. M.D.; Mealey, John Jr., M.D.; Neal, John H. M.D.; Olson, Jeffrey M.D.; Robertson, James T. M.D.; Barnett, Gene H. M.D.; Bloomfield, Stephen M.D.; Albright, Robert M.D.; Hochberg, Fred H. M.D.; Hiesiger, Emile M.D.; Green, Sylvan M.D.

Abstract:

OBJECTIVE : The objective of the Brain Tumor Cooperative Group NIH Trial 87-01 trial was to investigate the effect of additional implanted radiation therapy in newly diagnosed patients with pathologically confirmed malignant gliomas.

METHODS : The study involved a randomized comparison of surgery, external beam radiotherapy, and carmustine (BCNU) versus surgery, external beam therapy, interstitial radiotherapy boost, and BCNU in newly diagnosed malignant gliomas. 125I was chosen as best suited for this effort because it allowed preimplantation planning and postimplantation quality assurance review. Two hundred ninety-nine patients met the eligibility criteria and were randomized into the two arms of the study between December 1987 and April 1994. Follow-up continued for an additional 3 years. Twenty-nine patients were identified as having committed protocol violations and were excluded, resulting in 270 subjects in the Valid Study Group. One hundred thirty-seven patients received external beam radiation and BCNU, and 133 underwent the 125I implantation plus external beam radiation and BCNU therapy.

RESULTS : The overall median survival for the Valid Study Group was 64.3 weeks. The median survival for patients receiving additional therapy of 125I was 68.1 weeks, and median survival for those receiving only external beam radiation and BCNU was 58.8 weeks. The cumulative proportion surviving between the two treatment groups was not statistically significantly different (log-rank test, $P = 0.101$). As in other studies in the literature, age, Karnofsky score, and pathology were predictors of mortality. Additional analyses incorporating an adjustment for these prognostic variables, either in a stratified analysis or Cox proportional hazards model, did not result in statistically significant differences in the cumulative proportion of patients surviving between the two treatment groups.

CONCLUSION : We conclude that there is no long-term survival advantage of increased radiation dose with 125I seeds in newly diagnosed glioma patients.

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