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OT-34. Survival And Toxicity Update Of The Phase 2 Trial Of Bevacizumab (Bv) In Combination With Temozolomide (Tmz) And Radiation Therapy (Rt) Followed By Bv, Tmz, And Irinotecan (Cpt-11) For Newly Diagnosed Glioblastoma Multiforme (Gbm) Patients

Annick Desjardins, David A. Reardon, Katherine B. Peters, James E. Herndon II, John P. Kirkpatrick, Henry S. Friedman and James J. Vredenburgh

Duke University Medical Center

Abstract

BACKGROUND: Newly diagnosed glioblastoma multiforme (GBM) patients receiving temozolomide (TMZ) and radiation therapy (RT), followed by 6 monthly cycles of TMZ have median progression-free survival (PFS) and median overall survival (OS) rates of 6.9 and 15.9 months, respectively. Bevacizumab (BV) has demonstrated a significant therapeutic benefit for recurrent GBM. This study aimed to evaluate the benefit of incorporating BV with RT and TMZ, and CPT-11 and BV to TMZ post-RT therapy for newly diagnosed GBM patients.

METHODS: Patients received standard RT and TMZ at 75 mg/m^2/day, with BV at 10 mg/kg every 14 days beginning at least 28 days postoperatively. Afterward, patients received 6 to 12 cycles of TMZ, BV, and CPT-11 (28-day cycle). TMZ was given at a dose of 200 mg/m^2 on days 1–5, BV and CPT-11 were given on days 1 and 15; BV was given at a dose of 10 mg/kg and CPT-11 at a dose of 125 mg/m^2 for patients not on an enzyme-inducing antiepileptic drug (EIAED) and at a dose of 340 mg/m^2 for patients on an EIAED.

RESULTS: For the first 75 patients enrolled, at a median follow-up of 23 months, the median PFS is 14.5 months and the median OS is 21.2 months. One-year and 2-year OS are 79% and 45%, respectively. PFS rates at 1 and 2 years are 63% and 14%, respectively. For recursive partitioning analysis (RPA) class 3, 1-year OS was 100% and 2-year OS was 68%. For RPA class 4, OS dropped from 92% at 1 year to 39% at 2 years. Toxicities for all 125 enrolled patients included 1 CNS hemorrhage, 9 venous thromboembolisms, 2 wound dehiscences, 1 bowel perforation, 17 grade 4 hematologic toxicities, 1 secondary malignancy (AML), and 2 pneumonias of Pneumocystis jiroveci.

CONCLUSION: Adding BV to TMZ and RT followed by BV, TMZ, and CPT-11 is tolerable and efficacious. Updated survival and toxicity results for the whole group of 125 patients enrolled will be presented.

http://neuro-oncology.oxfordjournals.org/content/12/suppl_4.toc