NI-36. VALIDATION OF RANO CRITERIA: CONTRIBUTION OF T2/FLAIR ASSESSMENT IN PATIENTS WITH RECURRENT GlioBLASTOMA TREATED WITH BEVACIZUMAB

Raymond Huang1, Rifaquat Rahman1, Whitney Pope2, Benjamin Ellingson2, Karla Ballman3, Sara Felton3, S. Keith Anderson3, Lakshmi Nayak1, Eudocia Lee1, Lauren Abrey4, Evanthia Galanis1, David Reardon1, Timothy Cloughesy2, and Patrick Wen1; 1Brigham and Women’s/Dana Farber Cancer Center, Boston, MA, USA; 2University of California Los Angeles, Los Angeles, CA, USA; 3Mayo Clinic, Rochester, MN, USA; 4Roche, Basel, Switzerland

PURPOSE: Since its introduction, the RANO criteria have not been validated using outcome data from prospective trials. We examined the radiologic data of patients with recurrent glioblastoma treated with bevacizumab from the randomized phase II BRAIN trial (AVF3708g) to determine the effect of including T2/FLAIR evaluation in the RANO criteria on measurements of objective response rates (ORR) and progression free survival (PFS). METHODS: The imaging data of 163 patients with recurrent glioblastoma from the BRAIN trial were evaluated by 6 readers blinded to clinical information. The ORR and median PFS were determined using the RANO criteria and compared to those obtained using the Macdonald criteria. Landmark analyses were performed at 2, 4 and 6 months, and Cox proportional hazard models were used to determine the associations between OR and progression with subsequent survival. RESULTS: The ORRs were 0.331 (95% CI: 0.260 - 0.409) and 0.393 (95% CI: 0.317 - 0.472) by RANO and Macdonald criteria, respectively (p < 0.0001). The median PFS was 4.6 months (95% CI: 4.1-5.5) using RANO criteria, compared to 6.4 months (95% CI: 5.5-7.1) as determined by Macdonald criteria (p = 0.01). At 2-, 4-, and 6-month landmarks, both OR status and PFS determined by RANO criteria were predictive of overall survival (OS) (hazard ratios for 4-month landmark: OR HR = 1.93, p = 0.0012, PFS HR = 4.23, p < 0.0001). CONCLUSION: The inclusion of T2/FLAIR assessment in the RANO criteria results in moderate and statistically significant differences in median PFS and ORR. OR and PFS determined by RANO correlated with OS.