Annals of Oncology 27 (Supplement 4): iv107–iv125, 2016
doi:10.1093/annonc/mdw345.47

miscellanea

S47 A retrospective analysis to evaluted the off-label use Bevacizumab in recurrent malignant gliomas

A. Prelaj[1], S.E. Rebuzzi[2], M. Salvati[3], C. Pozzi[1], C. Ferrara[4], S. Tomao[5], V. Bianco[1]
[1]*Policlinico Umberto I, Roma*
[2]*IRCCS San Martino IST, Genova*
[3]*IRCCS Neuromed, Pozzilli*
[4]*Dipartimento Della Salute E Malattie Infettive, Roma*
[5]*Icot, Latina*

Background: No consensus therapy is recommended for recurrent malignant gliomas (MGs). In 2009, Bevacizumab (BEV), was approved by the FDA as a single-agent for the treatment of recurrent glioblastoma (GBM). Prospective and retrospective studies evaluated its efficacy as singel-agent or in combination with chemotherapy, both in recurrent GMB and anaplastic gliomas (AGs). Few data are available on the combination of BEV with fotemustine (FTM). The aim of this retrospective study was to evaluate the efficacy and the safety of BEV alone or in combination with FTM in the treatment of recurrent MGs patients.

Methods and patients: From August 2011 through May 2016 we analyzed 17 recurrent MGs patients, 12 (70.6%) GBM and 5 (29.4%) AGs. All patients underwent first-line therapy with STUPP regimen. BEV was administered (off-label use) in 13 patients in third line therapy after a second-line therapy with FTM and in 4 patients as a second-line therapy in association with FTM (3 patients) and dendritic vaccine (1 patients). BEV was administered at a dose of 10 mg/kg every 14 days. The Kaplan-Meier test was used to evaluate the PFS and OS.

Results: The median age 50 years (26-66), the median Karnofsky Performance Status 80 (60-100), the median number of cycles was 8 (2-40).One complete response (5.9%), 7 partial responses (41.2%), 3 stable diseases (17.6%) with a disease-control of 64.7% and 6 progression diseases (35.3%) were assessed using RANO criteria. Median PFS was 5 months (95% CI 2-7.9) with a PFS at 6 months of 41.2%. The meOS was 8.3 months (95% CI 3.9-12.6).The assessment of the O6-methylguanine methyltransferase (MGMT) gene promoter was conducted in 12 patients (70,6%). The methylated patients showed longer mPFS and mOS than unmethylated patients, without statistical signi?cance. Five patients experienced long response with a high number of administered cycles (range 18-40) and PFS (range 12-42 months). BEV was well-tolerated with proteinuria G1/G2 in 41.2% and 11.8% patients respectively. Only one patient developed proteinuria G3 after 30 cycles. Hypertension G1/G2 was observed in 35.3% and 11,8% of patients respectively. One patient developed pulmunary embolism.

Conclusion: This retrospective study confirms the safty and the benefit of BEV in patients with recurrent MGs, alone or in associations with FTM. In consideration of long-term responders observed we suppose there is a subgroup of selected patients who can benefit from BEV treatment. More study needed.