NI-26. COMPARATIVE ANALYSIS OF THE RANO AND MACDONALD’S CRITERIA IN RECURRENT GLIOBLASTOMA TREATED IN THE RANDOMIZED PHASE II TRIAL AVAREG WITH BEVACIZUMAB OR FOTEMUSTINE.

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BACKGROUND: RANO criteria, which evaluate both contrast enhancement and T2/FLAIR alterations, have been recently defined, but no prospective validation exists. We examined the radiological data of patients with recurrent glioblastoma treated with bevacizumab (BEV) or fotemustine (FTM) in the randomized phase II AVAREG-ML25739 (EUDRACT 2011-001363-46) trial. METHODS: All MRIs of the pts have been evaluated (BEV/FTM: 59/32) accordingly with RANO and Macdonald’s criteria, both locally and centrally. RESULTS: 223 MRIs were analyzed. Concordance between RANO and Macdonald criteria was found in 96.3% of cases at local evaluation and in 95.5% at central revision. Concordances between local and central assessments were 72.5% with RANO criteria and 71.1% with Macdonald’s criteria. At local evaluation, pts treated with BEV had a disease control rate (DCR = CR + PR + SD) of 0.75 (95%CI: 0.62-0.85) with RANO criteria, and 0.76 (95%CI: 0.63-0.86) with Macdonald criteria, vs 0.59 (95%CI: 0.41-0.76) and 0.63 (95%CI: 0.44-0.79) with FTM. Central evaluation showed a DCR of 0.80 (95%CI: 0.68-0.90) both with RANO and Macdonald criteria for pts treated with BEV vs 0.50 (95%CI: 0.32-0.68) with FTM. In the BEV arm, only 6.8% of patients showed an increase of T2/FLAIR without T1 contrast enhancement. CONCLUSIONS: After 4 years from RANO proposal, we showed that there is a good concordance of disease evaluation in recurrent glioblastoma pts treated either with BEV or FTM in academic centers.