RESULTS: Mean CXCL13 concentrations in CSF were 964.2 pg/ml (475.3–1481.1 pg/ml) and 54.9 pg/ml (<1–99.7 pg/ml) in PCNSLs and other brain diseases, respectively. CXCL13 levels in CSF were significantly increased in patients compared with other brain diseases (p<0.0001). At a CXCL13 cutoff level of 475 pg/ml, the sensitivity and specificity were 100% and 98%, respectively. CXCL13 levels were correlated with CSF IL-10 levels (p=0.0003) and CSF IL-6 levels (p=0.0033). Median OS and PFS in all treatment groups were 36 months, and 39% 12 months survival at 12 months (OS12), progression free survival (PFS) was measured from the start of study treatment until first PD according RANO criteria.

RESULTS: Between Oct 2011 and July 2013 274 patients were randomized. Baseline characteristics were well balanced, and all treatment groups were similar. Arm 4 received subsequent salvage BEV. Time to progression was longer in initially BEV treated patients, but survival was similar in all arms:

OS5.2 HEALTH-RELATED QUALITY OF LIFE (HRQoL) IN PATIENTS WITH PROGRESSIVE GLIOBLASTOMA TREATED WITH COMBINED BEVACIZUMAB AND LOMUSTINE VERSUS LOMUSTINE ONLY (RANDOMIZED PHASE III EORTC STUDY 26101)


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BACKGROUND: Progression-free survival, but not overall survival, was prolonged in the experimental treatment arm with bevacizumab and lomustine (BEV/LOM) compared to the lomustine only control (LOM) arm of the randomized EORTC 26101. Secondary outcomes, such as Health-Related Quality of Life (HRQoL), are important to determine a possible net clinical benefit of BEV in progressive glioblastoma.

OBJECTIVE: To evaluate the impact of treatment effects on HRQoL in recurrent glioblastoma patients treated in randomized phase III EORTC 26101.

METHODS: Recurrent glioblastoma patients were randomized, after standard radio-chemotherapy, to either BEV/LOM, or LOM (2:1 randomization). HRQoL was assessed using the EORTC core questionnaire (QLQ-C30) and brain module (QLQ-BN20). Assessments were performed at baseline, and every 12 weeks during treatment until progression of disease. Preselected scales for analysis were Global Health Status (GHS), Physical Functioning (PF), Social Functioning (SF), Motor Dysfunction (MD) and Communication Deficit (CD). Primary endpoint was HRQoL during the last assessment following baseline until week 36. In addition, mean changes from baseline to week 12, 24, and 36 were calculated as well as Time to HRQoL Deterioration (TTD) and HRQoL Deterioration Free Survival (DFS).

RESULTS: 402/437 patients (92%) had a HRQoL assessment at baseline. Compliance dropped to 66% at week 36, limiting further analysis, with no differences between treatment arms until week 36 with compliance in favor of BEV/LOM arm (71.2% versus 50%). At the last assessment, no differences were observed for pressure scales, apart from SF at last assessment being clinically relevant lower in the BEV/LOM arm (mean 66 versus 81, p=0.001). Of note, baseline score for SF was 66 in the BEV/LOM arm and 71 in the LOM arm, showing stable SF for patients in BEV/LOM arm and improved SF for patients in the LOM arm during follow up in HRQoL. Baseline value from LOM was not different between arms at week 12 and 24, but GHS and SF were clinically relevant lower in the BEV/LOM arm at week 36 (mean change -5.6 versus +4.6 for GHS and -1.1 versus +9.3 for SF, in the BEV/LOM arm [n=35] and LOM arm [n=9] respectively, likely driven by low patient numbers in the LOM arm. TTD, not including progression as an event, was not different between treatment arms (median 13 weeks versus 13.1 weeks in the BEV/LOM and LOM arm, respectively; p=0.48). In contrast to DFS, with a significantly longer DFS in the BEV/LOM arm (median