

Radiotherapy remains the treatment of first choice for high-risk low-grade glioma

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In a large, international, randomized trial, initial radiotherapy was compared to temozolomide chemotherapy. A statistically significant difference between the two treatment strategies was not observed for progression-free survival, although radiotherapy was numerically favored. However, molecular tumor characterization may allow the treatment approach to be personalized and one or the other treatment modality to be selected.

The results of EORTC trial 22033-26033 will be presented Saturday, 01 June 2013 at an ASCO 2013 Oral Abstract Session by the coordinator of the study Brigitta Baumert, MD, PhD of the Radiation [Oncology](#) Department, Maastricht University (MAASTRO) and recently appointed deputy head of the Radiotherapy Department of the MediClin Robert-Janker Clinic, Clinical Cooperation Unit Neurooncology & University of Bonn Medical Center, Germany. In this trial, 477 patients from 18 countries were randomized (after molecular stratification for 1p-status) between radiotherapy (240 patients) and chemotherapy with temozolomide (237 patients), a drug which has been shown to have an activity in low-grade glioma. The trial results show that first line treatment with temozolomide compared to radiotherapy does not improve progression-free survival in these high-risk low grade glioma patients.

Dr. Baumert states, "This is the first study in primary brain [tumor](#) to prospectively evaluate molecular markers. In the future, diagnosis of low-grade glioma will be substituted by a more differentiated molecular

tumor characterization upon which treatment strategies will depend. The data are preliminary – as median overall survival has not yet been reached. Good wine needs aging..."

Outcome for patients with low-grade glioma varies widely. In previous randomized trials the EORTC and others have shown that treatment can be deferred in patients without additional risk factors. For higher risk patients, radiotherapy might be of value. EORTC trial 22033-26033 was designed for patients with a prognostic profile that indicated a poor outcome and investigated whether primary [chemotherapy](#) as compared to standard [radiotherapy](#) would prolong progression-free and overall survival.

The study also sought to identify prognostic molecular factors that might assist in making treatment decisions. At the time of study conception, the prognostic importance for tumor response to treatment in the presence of a chromosomal deletion on the short arm of chromosome 1 was known, and consequently patients were stratified before randomization. Other markers will be analyzed now that the study is complete and will clarify why some patients have a much better disease evolution than others.

"This is a very important study in our quest to personalize [treatment strategies](#). The ongoing molecular tumor characterization will identify individual characteristics guiding future treatment decisions – be it intensifying therapy for some, or withholding therapy for others", said Roger Stupp, Director of the Zurich University Cancer Center, President of the EORTC and one of the Principal Investigators of the study.

At a median follow-up of 45.5 months and after the tumors of 246 patients had progressed, there was no statistical difference in progression-free survival, the primary endpoint. Overall toxicity was mild. Grade 3 hematological toxicity was observed in 9% of the temozolomide treated

patients.

Secondary analyses included overall survival and the impact of 1p status. Median overall survival is not yet reached, but 1p deletion was confirmed to be a positive prognostic factor with either treatments (p-value stratified by treatment, progression-free survival: $p = 0.0003$; HR = 0.59, 95% CI (0.45 - 0.78), overall survival: $p = 0.002$; HR = 0.49, 95% CI (0.32 - 0.77)). Although the interaction test was not significant, for patients treated with temozolomide, there was a trend for inferior progression-free survival in patients who had 1p intact, and overall survival may be better for [patients](#) who had the 1p deletion. The [survival](#) analyses require further maturation and more molecular data (1p/19q, IDH1 etc.) to further characterize the responders to temozolomide therapy and guide [treatment](#) decision. Analyses of molecular profiles, neurocognition and quality-of-life are ongoing.

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