

V761 - Zwei Jahre Rituximab-Erhaltung vs. Beobachtung nach Erstbehandlung mit Bendamustin-Rituximab (B-R) bei Patienten mit Marginalzonenlymphom (MZL): Ergebnisse einer prospektiven, randomisierten, multizentrischen Studie (StiL NHL7-2008 MAINTAIN) / Two years Rituximab maintenance vs. observation after first line treatment with bendamustine plus rituximab (B-R) in patients with marginal zone lymphoma (MZL): results of a prospective, randomized, multicenter phase 2 study (the StiL NHL7-2008 MAINTAIN trial)

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Introduction: Rituximab (R) maintenance is part of a standard treatment for follicular lymphoma. In MZL, however, it is not yet common practice. In this study we compared the effect of 2 years of R maintenance vs. observation after first-line treatment with B-R in patients with previously untreated MZL.

Methods: Patients had stage II (bulky disease >7 cm), III, or IV disease. Nodal and splenic MZL were included but not MALT lymphomas. Primary endpoint was progression free survival (PFS). Secondary endpoints included response rates, overall survival (OS), and toxicity. For induction patients were treated with up to 6 cycles of B-R plus 2 additional R cycles. Only patients responding to B-R were then randomized to either R maintenance (q 2 months for 2 years) or observation.

Results: Median time of follow-up after registration was 76 months at the time of this analysis (February 2018). 119 patients with a median age of 65 years were evaluable for response. 108 (91%) responded to B-R induction, with 23 patients (19%) achieving a complete remission. Of 104 randomized patients, 53 (51%) were randomized to R maintenance and 51 (49%) to observation. Median age of randomized patients was 64 years, patient characteristics and toxicity were similar for both groups. PFS was superior for 2 years of R maintenance, with the median not yet reached vs. 83.9 months for observation (hazard ratio (HR) 0.33, 95% CI 0.16 - 0.73, p = 0.006). The OS rate at 6 years was 92% for R maintenance vs. 86% for observation. The difference in OS was not statistically significant (HR 0.53, 95% CI = 0.20 - 1.43).

Conclusion: Our results demonstrate a statistically significant PFS improvement of a 2-year R-maintenance vs. observation after B-R induction in patients with MZL.