

Freier Vortrag - Niedrigmaligne B-Zell-Lymphome - Klinik

V390 - Two years Rituximab maintenance vs. observation after first line treatment with bendamustine plus rituximab (B-R) in patients with mantle cell lymphoma: first results of a prospective, randomized, multicenter phase 2 study (a subgroup study of the StiL NHL7-2008 MAINTAIN trial; Clinicaltrials.gov Identifier: NCT00877214)

Rummel M.¹, Knauf W.², Goerner M.³, Söling U.⁴, Lange E.⁵, Hertenstein B.⁶, Eggert J.⁷, Schliesser G.C.⁸, Weide R.⁹, Blumenstengel K.¹⁰, Detlefsen N.¹¹, Hinke A.¹², Kauff F.¹³, Barth J.¹³, Studiengruppe indolente Lymphome (StiL)

¹Justus-Liebig-Universität, Universitätsklinik, Med. KI IV, Gießen, Germany, ²Onkologische Praxis, Frankfurt, Germany, ³Städtisches Klinikum, Bielefeld, Germany, ⁴Onkologische Praxis, Kassel, Germany, ⁵Evangelisches Krankenhaus, Hamm, Germany, ⁶Klinikum Bremen Mitte, Hämatologie und Onkologie, Bremen, Germany, ⁷Onkologische Praxis, Moers, Germany, ⁸Onkologische Praxis, Gießen, Germany, ⁹Praxis für Hämatologie und Onkologie, Koblenz, Germany, ¹⁰Praxis für Hämatologie und Onkologie, Eisenach, Germany, ¹¹Justus-Liebig-Universität, Universitätsklinik, Gießen, Germany, ¹²WiSP, Wissenschaftlicher Service Pharma GmbH, Langenfeld, Germany, ¹³Justus-Liebig-Universität, Universitätsklinik, Hämatologie, Med. KI. IV, Gießen, Germany

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

Methods: Patients were required to have stage II (with bulky disease >7 cm), III, or IV disease for registration in this study. Primary endpoint was progression free survival (PFS). Secondary endpoints included response rates, overall survival (OS), time to progression, event free survival, toxicity. Patients were treated with up to 6 cycles of B-R plus 2 additional cycles rituximab. 122 Patients who have responded to B-R were then randomized to either rituximab maintenance (375 mg/m² every 2 months for a total of 2 years) or observation only.

Results: A total of 118 patients were evaluable for the analysis, 58 (49%) were randomized to maintenance with rituximab and 60 (51%) to observation, respectively. Patient characteristics were comparable for both groups. Median patient age was 71 years, median time of observation was 57,7 months at the time of this analysis (April 2016).

No statistical significant differences in PFS between both arms could be observed (p=0.211, 49 events, HR 0.70, 95% CI 0.40 - 1.22). The median PFS for R maintenance was 74.8 months (95% CI 65.4 - nyr). For the observation arm the median PFS was 54.7 months (95% CI 40.1 - n. y. r.). The results for overall survival showed no difference (p=0.338, 27 events, HR 1.45, 95% CI 0.68 - 3.10) with a median of nyr for both arms.

Conclusions: After a median observation time of 4.8 years from 1st cycle B-R, the results are yet inconclusive. Up to date we were not able to demonstrate a statistical evidence supporting the benefit of R maintenance after B-R in the treatment of patients with MCL. Longer follow-up is needed before final results can be presented.

Disclosure: Mathias Rummel: Advisory Role: Mundipharma, Roche; Financing of Scientific Research: Mundipharma, Roche
Jürgen Barth: Financing of Scientific Research: Mundipharma, Roche

Angaben für Zitate:

- Titel des Abstracts, siehe oben
- Namen der Autoren, siehe oben
- Abstract-Nr., siehe oben
- Quelle: Abstract-USB-Stick Jahrestagung der Deutschen, Österreichischen und Schweizerischen Gesellschaften für Hämatologie und Medizinische Onkologie 2016
- ISSN 1863-1819