



MCL

ASCO 2016 | MAINTAIN Trial First Results – Rituximab Versus Observation for Maintenance in Patients with MCL

 Terri Penfold | Nov 15, 2016

This [ASCO 2016 oral abstract presentation](#) took place on Sunday June 5, 9:45am–12:45pm, during the [‘Hematologic Malignancies-Lymphoma and Chronic Lymphocytic Leukemia’ session](#). This session was chaired by [Pr Gilles Salles](#), Head of the [Hematology Department in South Lyon hospitals](#), Lyon, France.

The abstract ([#7503](#)) was presented by Dr [Mathias J Rummel](#), head of the Department of Hematology at the Clinic for Hematology and Medical Oncology at the [Justus-Liebig University-Hospital](#), Gießen, Germany.

In FL, maintenance rituximab is a standard care option; however, this is not the case for MCL. A prospective, randomized, multicenter study ([NCT00877214](#)) was initiated to investigate observation compared to maintenance rituximab following induction with bendamustine-rituximab in newly diagnosed MCL patients.

Beginning in April 2009, this study’s primary outcome measure was PFS. Inclusion criteria consisted of: stage II (with bulky disease >7 cm), III, or IV disease; CD20+ lymphoma verified by histological analysis; general condition WHO 0–2; and age between 18–80 years.

Induction of up to 6 cycles of bendamustine-rituximab was administered to patients, and the 122 who responded were randomized to either 375mg/m² rituximab every 2 months for 2 years (n=60) or observation only (n=62).

- Median age = 70 years
- Median follow-up = 58.6 months
- No significant difference was found for PFS between the 2 arms
- Median PFS: rituximab pts = 72.3 months (21 events); observation pts = 54.7 months (29 events; HR, 0.71; 95% CI, 0.41–1.23; *P* = 0.2267)
- No significant difference was found for OS between the 2 arms
- Median OS: rituximab pts = not reached (11 events); observation pts = not reached (15 events; HR, 1.51; 95% CI, 0.70–3.25; *P* = 0.2974)

Once again, the superb efficacy of bendamustine-rituximab was demonstrated in elderly patients with MCL. However, no significant difference in PFS or OS was found between the rituximab maintenance and observation arms. Therefore, it was concluded that there is no evidence to support the use of rituximab maintenance after bendamustine-rituximab in elderly MCL patients. Furthermore, the activity of bendamustine-rituximab without maintenance rituximab appeared comparable to R-CHOP plus maintenance rituximab (PFS and OS).

Reference

1. Rummel MJ, *et al.* 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 II study (a subgroup study of the StiL NHL7-2008 MAINTAIN trial). J Clin Oncol 34, 2016 (suppl; abstr 7503).

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