



DLBCL

ASCO 2016 | Early Intensification of Rituximab Plus 2-Weekly CHOP Showed No Significant Improvement to CR or PFS in Patients with Stage II-IV DLBCL

 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 ([#7504](#)) was presented by Dr [Pieternella J Lugtenburg](#) of [Erasmus MC](#), Rotterdam, Netherlands.

In patients with Diffuse Large B-Cell Lymphoma (DLBCL), the standard care option is R-CHOP. However, the optimal rituximab dose and schedule is yet to be determined. A randomized, phase III study (NTR number: [1014](#)) was initiated to compare standard R-CHOP-14 and R-CHOP-14 with 4 additional rituximab administrations (375mg/m² IV on day 8) during the initial 4 cycles.

It was hypothesized that better response rates (CR) will be achieved in the early intensification of rituximab plus 2-weekly CHOP arm (arm B) than the standard arm (arm A). The primary endpoint was metabolic complete remission rate after induction treatment.

Inclusion criteria for this study included: confirmed histologic diagnosis of DLBCL according to WHO classification, CD20+, Ann Arbor stages II–IV, and age range of 66–80 years. Patients in CR after induction treatment were randomized between observation and rituximab maintenance.

During this talk, the efficacy results of the first randomization were presented.

- Overall, 575 pts randomized: Arm A = 286 pts; Arm B = 289 pts; baseline patient and disease characteristics were well balanced
- Median age = 65 years (range, 18–80); ≥66 years = 50% pts; male = 52%
- High-intermediate or high aa-IPI score = 57%
- CR: Arm A = 84%; Arm B = 82% (OR, 0.83; 95% CI, 0.54–1.28; *P* = 0.40)
- Observed CR rates for pts ≤65 or >65 years old were identical
- Median follow-up = 49 months (maximum 90 months)
- 3-year PFS: Arm A = 74%; Arm B = 71%
- 5-year PFS: Arm A = 68%; Arm B = 61% (HR, 1.23; 95% CI, 0.92–1.63; *P* = 0.16)

- No significant improvement in PFS was found in subgroups by age (≤ 65 or >65 years) or gender
- OS: Arm A = 69%; Arm B = 92% (HR, 1.36; 95% CI, 0.99–1.86; $P = 0.06$)

Intensified compared to standard rituximab did not improve CR rate, OS or PFS. In addition, no benefit was observed in any of the clinical subgroups (age or gender). Intensification of rituximab resulted in more toxicity in patients aged between 66 and 80 years, in particular neutropenia during cycles 1–4, vs. standard rituximab. [Pieternella Lugtenburg](#) concluded the talk by stating that intensification of rituximab is of no benefit.

Reference

1. Lugtenburg PJ, *et al.* Randomized phase III study on the effect of early intensification of rituximab in combination with 2-weekly CHOP chemotherapy followed by rituximab or no maintenance in patients with diffuse large B-cell lymphoma: results from a HOVON-Nordic Lymphoma Group study. *J Clin Oncol* 34, 2016 (suppl; abstr 7504).

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