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R-CHOP14 COMPARED TO R-CHOP21 IN ELDERLY PATIENTS WITH DIFFUSE LARGE B-CELL LYMPHOMA: RESULTS OF THE INTERIM ANALYSIS OF THE LNH03-6B GELA STUDY

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In 2000 the GELA showed the survival advantage of R-CHOP21 over CHOP21 in the treatment (tt) of DLBCL in elderly patients (pts). The Germans have shown a superiority of CHOP14 over CHOP21 and R-CHOP14 over CHOP14. Here we report the results of the planned interim analysis (202 pts) of a phase III trial comparing R-CHOP14 to R-CHOP21. Pts between 60 and 80 y.o. with DLBCL and aalPI ≥ 1 were randomized between R-CHOP given every 2 or 3 weeks for 8 cy. G-CSF was given according to MD decision. Primary objective: to evaluate EFS. Secondary: OS, PFS, DFS, response rate and analysis of dose-intensity and toxicity. Sample size was calculated to demonstrate an improvement of 2 y EFS from 55% to 65% with R-CHOP14. 600 pts recruited over 4 y and followed for a min. of 1 y, will provide 80% power at the overall 5% (2-sided) significance level to detect the expected difference. 103 pts received R-CHOP14 and 98 R-CHOP21. Median age: 72y Pts' characteristics similar in 2 groups. Median interval between cycles was 15d. in R-CHOP14 and 21d. in R-CHOP21; 73 pts (71%) in R-CHOP14 and 74 pts (76%) in R-CHOP21 completed 8 cycles without progression. In the R-CHOP14, the increase of dose-intensity at the end of tt, calculated according to 3-week interval was 125% for cyclophosphamide and doxorubicin. 90% of pts treated with R-CHOP14 received G-CSF whereas only 66% in R-CHOP21. RR (CR+Cru) was 67% in R-CHOP14 and 75% in R-CHOP21 (p=NS). The 2-y EFS was 48% in R-CHOP14 and 61% in R-CHOP21 (p=NS). Similar trend was seen for 2-y PFS (49% vs 63%), 2-y DFS (57% vs 70%) and 2-y OS (67% vs 70%) (p=NS for all). Grade 3-4 hematological toxicity was more frequent in R-CHOP14 with more pts receiving transfusions and/or experiencing FN, resulting in higher proportion of pts hospitalized for AE. No difference for extra-hematological grade 3-4 toxicities. Results of this interim analysis trial favor tt with R-CHOP21 in elderly pts with trends toward higher efficacy and lower toxicity compared to R-CHOP14.