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Poster Display session

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955P - Interim analysis of an ongoing phase II trial assessing safety and efficacy of R-IDEA as salvage therapy in patients with relapsed/refractory DLBCL: An intergroup study of the society of lymphoma treatment in Japan (SoLT-J) and the west Japan hematology/o

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Aim

High dose chemotherapy (HDT) with autologous stem cell support (ASCT) has been proven effective in relapsed(rel)/refractory(ref) Diffuse large B cell lymphoma (DLBCL), but the benefit is limited to the patients (pts) who are sensitive to salvage chemotherapy (CTx) and are able to mobilize sufficient peripheral blood stem cells (PBSCs). The salvage CTx regimen IDEA was previously reported as effective (ORR; 67.6%) and feasible to mobilize PBSCs (77.8%). (Nishimori et al. Anticancer Res 2009) Accordingly, we designed a multicenter phase II trial addressing safety and efficacy of IDEA plus Rituximab(R) in rel/ref DLBCL pts (UMIN000004892). Herein, we report the interim analysis on the first 20 enrolled pts.

Methods

This study includes pts aged 18-65 years with primary refractory or first relapse CD20⁺ DLBCL after anthracycline-containing CTx. The R-IDEA regimen consists of R 375mg/m² on day 1, IFO 1.3g/m², ETP 150mg/m² on days 2-4, Dex 33mg IV on days 2-5 and Ara-C 750mg/m² twice daily on days 3-4. R-IDEA was administered every 21 days for a total of 3 cycles. PBSCs were harvested after cycle 3. Pts in a CR/PR after R-IDEA and who got successful mobilization (>2 million of CD34⁺ cells/kg) received HDT/ASCT. Primary endpoint was mobilization adjusted response rate (MARR; [CR] + [PR] -

mobilization failure).

Results

20 pts were enrolled (median age 59.5, range 42-65; M:F ratio 11:9). 17 pts were enrolled after first relapse and three were primary refractory. 5 pts relapsed within 1 year from initial diagnosis. The most frequent grade 3/4 adverse events were neutropenia (55/56 cycles), thrombocytopenia (46/56 cycles), anemia (24/56 cycles), and febrile neutropenia (26/56 cycles). No other grade 5 adverse event occurred. After completion of R-IDEA, 7 pts (35%) achieved CR, 5 (25%) PR, one had SD, and 7 had PD. The median CD34⁺ count was 2.64 million/kg (range: 0.17-43.7). 3 pts failed to mobilize >2 million of CD34⁺ cells/kg, for a MARR of 45% (9/20). No patient of primary refractory or relapsed within 1 year after initial diagnosis and 9 pts relapsed >1 year from diagnosis achieved mobilization adjusted response (p = 0.001). The nine pts proceeded to HDT/ASCT.

Conclusions

R-IDEA is feasible and well tolerated in pts with rel/ref DLBCL. Primary refractory and early relapsed DLBCL pts had a poorer prognosis. New treatment strategy seems to be warranted for the high risk pts.