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Title: **BENDA-BEAM HIGH-DOSE THERAPY PRIOR TO AUTO-SCT IS EFFECTIVE IN RESISTANT/RELAPSED DLBCL: A PHASE II STUDY**

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Text: **Background:** A major drawback affecting clinical trials of high-dose therapy (HDT) followed by autologous stem cell transplant (ASCT) in lymphomas is the high heterogeneity of histological entities. As a consequence, the statistical power is reduced when we focus on a specific histological subset, and data are often not conclusive. We designed a phase II study to evaluat the efficacy of the BeEAM conditioning (bendamustine 200 mg/m2 on days -7,6, cytarabine 40(mg/m2 days -5-4-3-2, etoposide 200 mg/m2 days -5-4-3-2, melphalan 140 mg/m2 day-1) in resistant/relapsed diffuse large B-cell non-Hodgkin lymphoma (DLBCL) patients.
Methods: The study was registered at European Union Drug Regulating Authorities Clinical Trials (EudraCT) N. 2011-001246-14. 64 patients (median age 54.5 years, range 19-70) with resistant/relapsed DLBCL or transformed follicular lymphoma were enrolled. The primary end-point of the study is to evaluate the 1-year complete remission rate.
Results: Briefly, 47/64 patients had advanced stage disease (III-IV); 21 were primary refractory and 43 had relapsed. 33/64 were in II or subsequent CR after salvage therapy, whereas 24 wer in PR and 7 in progressive disease. A median number of $5.55x10^6$ CD34+/Kg cells (range 2.07 12.20) collected from peripheral blood was reinfused to patients. All patients engrafted, with a median time to ANC>$0.5x10^9$/l of 10 days. Median times to achieve a platelet count >$20x10^9$/l and >$50x10^9$/l were 13 and 18 days respectively. Twenty-four out of 64 patients presented a FUO (37.5%). One patient died due to an incomplete hematological recovery after transplant and one patient died due to acute liver failure, producing an overall transplant related mortality 3.1%. Sixty-two patients are evaluable for response: 51/62 (82%) obtained a CR, 4/62 (6%) a PR, whereas 7/62 (11%) did not respond to therapy. The median follow-up after transplant was 34 months (range 1-90).
Conclusions: The stringent inclusion criteria at enrollment allow to precisely evaluate the impact of HDT with Bendamustine followed by ASCT in a highly selected population of patients with DLBCL. The 1 year remission rate was superior to 55% , thus reaching the primary end-point. Accordingly, our data provide the evidence that the Benda-BEAM regimen is safe and ha promising high efficacy in resistant-relapsed aggressive diffuse large B cell lymphoma.
Disclosure: Nothing to declare

Keywords: autologous stem cell transplantation, diffuse large B cell lymphoma, high dose chemotherapy, refractory lymphoma

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