TO21 (0017) B-CAP (BRENTUXIMAB VEDOTIN, CYCLOPHOSPHAMIDE, DOXORUBICIN AND PREDNISOL (LO) NEKALO) OLD-INT Group: TREATMENT OF ADVANCED STAGE HODGKIN LYMPHOMA: RESULTS OF A PHASE II INTERGROUP TRIAL BY THE GERMAN HODGKIN STUDY GROUP (GHSG) AND THE NORDIC LYMPHOMA GROUP (NLG)

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Background: About 20% of patients diagnosed with classical Hodgkin lymphoma (cHL) are 60 years or older. They have a comparatively poor prognosis, particularly when presenting in advanced stages. In previous trials, older patients did not benefit from intensified regimens in terms of overall survival due to a high toxicity-related death rate. In order to improve tolerability, we developed the B-CAP regimen (brentuximab vedotin, cyclophosphamide, doxorubicin and prednisolone) incorporating the antibody-drug conjugate brentuximab vedotin into a CHOP-based chemotherapy backbone. We report the first results of our multicenter phase II study evaluating B-CAP in older cHL patients.

Methods: We recruited patients with newly diagnosed advanced-stage cHL aged 60 years or older and eligible for polycythemia (Cumulative Illness Rating Scale for Geriatrics ≤5 in total and ≤3 per organ system) in five European countries. Treatment consisted of six cycles B-CAP; radiotherapy to Positron Emission Tomography (PET) positive deposits. The primary endpoint was the CT-based objective response rate (ORR; complete [CR] or partial remission [PR]) after six cycles of B-CAP, aiming at excluding an ORR of 60% or less via a one-sided 95% confidence interval. All patients completing interim staging after two cycles were considered eligible.

Results: Between November 2015 and September 2017, 50 patients were recruited, of whom one withdrew consent before start of treatment. Of the remaining 49, 26 patients (53%) were male, 47 (96%) had stage III-IV disease, and the median age was 66 years (range 60–84). One patient died 8 months after interim staging, and 48 patients were eligible for the primary endpoint. There were no further treatment-related deaths. The CT-based ORR was 98% (one-sided 95% confidence interval 91%–100%) with 21 patients having CR, 26 patients having PR, and one patient having progressive disease in restaging after completion of B-CAP therapy. All patients with CT-based CR and 10/26 patients with PR had a negative PET (Deauville ≤4), resulting in a complete metabolic response rate of 65%. Dose delivery was high with only two patients stopping treatment after four and five cycles, respectively, due to toxicity. Progression-free and overall survival as well as safety data will be presented.

Conclusion: B-CAP is feasible and effective in patients older than 60 years with advanced-stage cHL and should be subject of further research.

PO69 (0013) EVALUATION OF CLINICAL CHARACTERISTICS IN PATIENTS WITH INTERIM-PET NEGATIVE BUT POSITIVE END OF TREATMENT PET. DATA FROM THE PROSPECTIVE HD08-01 FIL STUDY


On behalf of Fondazione Italiana Linfomi

Purpose: The clinical impact of positron emission tomography (PET) performed early during therapy in patients with advanced-stage Hodgkin lymphoma has confirmed its impact in progression free survival. It is disappointing the observation of a group of patients with negative interim-PET (i-PET) but with a positive PET at the end of induction therapy (e-PET). These patients underline that i-PET is not a perfect instrument and it could be very important to analyze their clinical or biological characteristics to identify them.

Patients and Methods: The phase II part of the multicenter HD0801 study involved 519 patients with advanced-stage de novo Hodgkin lymphoma who received an initial treatment with ABVD and underwent a i-PET. Patients with positive i-PET shifted to a salvage therapy and those with negative i-PET continued with standard treatment. Patients with negative i-PET were evaluated for response and patients with a positive e-PET were moved to a salvage therapy. The aim of this study was to evaluate clinical and biological characteristics of these patients.

Results: In all 409 were i-PET negative. Among them 16 interrupted the therapy for different causes, therefore 393 patients were evaluated with e-PET, 354 were negative and 39 were positive. Sixteen out 39 were submitted to a diagnostic biopsy and 15 were confirmed as HD; 23 did not performed biopsy due to technical difficulties or decision of the clinicians. Seventeen out 39 e-PET were reviewed according Deauville Score and in six it was confirmed positive (10 DS 5, 6 DS 4) in 1 case was invaluable. With the exception of LDH value at diagnosis no clinical characteristics were significantly different in comparison with e-PET negative patients. The survival of e-PET positive patients was very disappointing 78% at 36 months in comparison either with negative e-PET or with positive i-PET.

Conclusion: Positive e-PET represents a very bad prognostic event even in comparison with i-PET positive patients salvaged with intensified therapy. We must consider carefully this little group of patients in which...