Freie Vorträge: Follikuläres Lymphom

V799 - Therapy of relapsed hairy cell leukemia and hairy cell leukemia variants with cladribine plus rituximab

Rummel,M. J.[1], Menne,S.[1], Balser,Chr.[2], Kofahl-Krause,D.[3], Gaska,T.[4], Rothmann,F.[5], Strumberg,D.[6], Köchling,G.[7], Gärtner,F.[8], Welslau,M.[9], Niederle, N.[10], Müller,L.[11], Heidemann,E.[12], Pielke,H.[13], Barth,J.[1]

[1]Universitätsklinikum, Gießen, Deutschland; [2]Hämatologische/ Onkologische Praxis, Marburg, Deutschland; [3]MHH, Hannover, Deutschland; [4]Brüderkrankenhaus St. Josef, Paderborn, Deutschland; [5]Ernst von Bergmann Klinikum, Potsdam, Deutschland; [6]Marienhospital, Herne, Deutschland; [7]Hämatologische/ Onkologische Praxis, Villingen, Deutschland; [8]Universitätsklinikum, Freiburg, Deutschland; [9]Hämatologische/ Onkologische Praxis, Aschaffenburg, Deutschland; [10]Klinikum, Leverkusen, Deutschland; [11]Hämatologische/ Onkologische Praxis, Leer, Deutschland; [12]Diakonie-Klinikum, Stuttgart, Deutschland; [13]St. Johannes-Hospital, Dortmund, Deutschland

Introduction: Patients with relapsed hairy-cell leukaemia (HCL) can be successfully re-exposed to cladribine (2-CdA) even after previous therapy with 2-CdA. Additionally, CD20, a target for rituximab, is highly expressed on HCL-cells. Rituximab has shown some promising activity as a monotherapeutic agent in relapsed cases. The Studiengruppe indolente Lymphome (StiL) studies whether the combination of both compounds can be used in treating relapsed HCL as well as for the therapy of HCL-Variants (HCL-V). The latter is more aggressive than the "classical" HCL and is hard to treat.
Methods: The StiL's NHL 4 Study investigates the effectiveness (rate of complete remission, overall remission rate [ORR], and duration of remission) and toxicity (acute and long-term toxicity) of the combined antibody/chemotherapy with subcutaneous 2-CdA plus rituximab in patients with relapsed HCL, which required treatment, or with HCL-V. Additional objectives included treatment-associated immune deficiency (CD4/CD8), the duration and frequency of infections and other complications, the incidence of secondary malignancies during lifelong surveillance, and the overall survival rate. The Study NHL 4 is a prospective multicenter phase-II-study.
Treatment: Rituximab, 375 mg/m² on days 1, 8, 15, and 22 as an intravenous infusion with 2-CdA, 0.14 mg/kg on days 8-12 as a subcutaneous bolus injection. If a complete remission (CR) is maintained 4 months after treatment cessation, no additional cycles are administered. In case of partial remission (PR) or hairy cells in the sense of a MRD (minimal residual disease) and a well-tolerated previous therapy, a second cycle of 2-CdA plus rituximab, with the same dosage will be administered.
Results: The study started in 2004. Of the 65 enrolled patients, 48 are currently being evaluated. Six patients have HCL-V. The median of previous therapies is two. The ORR is 96%. The CR rate is 75% with 7 patients (14%) having achieved a CR yet showing MRD characteristics. The PR rate was 21%. In total, three disease-related deaths occurred in the PR group (4.6% of entire cohort) due to disease progression 3, 8, and 19 months following therapy initiation; however, initially, all patients showed improvement. The first died as a consequence of spinal cord myelosis, after 18 months of remission. The second patient died eight months after the start of therapy due to spleen infarction, subsequent to haemogram deterioration and pneumonia. The third died due to spleen infarction, cerebellar ischemia, and pancytopenia-associated hemorrhagic shock. All CRs are ongoing.
Conclusions: The proposed immuno-chemotherapy involving 2-CdA plus rituximab is effective in treating relapsed HCL and appears to be well tolerated. At present, there is no evidence of a sustained immune deficiency or a considerably higher rate of infections. Further updated data will be presented at the meeting.

Disclosure:
Rummel,M. J.
Anstellungsverhältnis oder Führungsposition:Leiter der Hämatologie, Gießen.
Barth,J.
Anstellungsverhältnis oder Führungsposition:Leiter der Studienzentrale