8026 Poster Discussion Session (Board #6), Sat, 8:00 AM-12:00 PM and 12:00 PM-1:00 PM

Multicenter, phase II study of bendamustine in refractory or relapsed T-cell lymphoma: The BENTLY trial.

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Background: T-cell lymphomas have a poor prognosis with few options of effective treatment. This study determined the efficacy and safety of bendamustine as a single agent in the treatment of refractory or relapsed T-cell lymphomas. **Methods:** Patients with histologically confirmed peripheral T-cell lymphoma (PTCL) or cutaneous T-cell lymphoma (CTCL), who had previously received at least one line of chemotherapy were selected. Bendamustine was administered IV at the dosage of 120 mg/m^2 on days 1 and 2 every 3 weeks, for 6 cycles. Treatment response was assessed using the IWC for non-Hodgkin's lymphoma. The primary end point was overall response rate (ORR). Secondary end points were duration of response (DoR), progression-free survival (PFS), and overall survival (OS), NCT00959686. **Results:** Twenty two female and 38 male were included. The median age was 66 years with more 1/4 of them $>$ 75. Histology was predominantly angio-immunoblastic lymphadenopathy (n=32) and PTCL-nos (n=23). The median previous line of chemotherapy was 1 (1-3). Nearly one half (45%) of the patients was refractory to the last previous chemotherapy and the median duration of the best previous response was 6.6 (1.5-67) months. The disease was disseminated in the majority of case (87%) and the international prognostic index (IPI) was high (3–5) in 68% of the patients. Twenty patients (33%) received less than 3 cycles of bendamustine. The major reason for early discontinuation was disease progression. In the Intent-To-Treat (ITT) population, the best ORR was 50%, including complete response (CR) in 28% and partial response (PR) in 22 %. Bendamustine showed a consistency in the efficacy as a function of major disease characteristics. The median values for DoR, PFS and OS were 3.5, 4 and 6 months respectively. The most frequent grade 3/4 AEs were neutropenia (30%), thrombocytopenia (24%) and infections (20%). **Conclusions:** Bendamustine is active in high risk refractory and relapsed T-cell lymphoma with manageable toxicity.