

[2127] Pentostatin, Cyclophosphamide, and Rituximab (PCR) Has Comparable Activity but Appears To Be Better Tolerated Than Fludarabine, Cyclophosphamide, and Rituximab (FCR) in Patients with Previously Treated Chronic Lymphocytic Leukemia.

Session Type: Poster Session 331-II

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Combination therapy with purine analogs, alkylators, and monoclonal antibodies has transformed the treatment paradigm in patients with CLL by dramatically enhancing both the quality and frequency of responses that can be achieved in these patients. However, combinations utilizing fludarabine

as the purine analog have augmented myelosuppression and immunosuppression requiring careful attention to dosing and schedule in order to minimize these complications. Even with these precautions many patients are unable to complete the entire treatment program at full dose and for the planned number of cycles. Comparative experience with pentostatin indicates that it is less myelosuppressive than either fludarabine or cladribine. We previously reported our experience with pentostatin and cyclophosphamide. Subsequently, we have added rituximab to this active combination (PCR regimen) and treated a second cohort of 46 patients with

previously treated CLL (32 patients) and other low grade lymphoid neoplasms (14 patients). The PCR regimen consists of pentostatin 4mg/m², cyclophosphamide 600mg/m², and rituximab 375mg/m² all given on a single day with anti-emetics, hydration, and careful monitoring of renal function. The treatment was administered every 3 weeks for a total of 6 treatments. Rituximab was not given during the first cycle to reduce the frequency and severity of infusion reactions. Filgrastim, sulfamethoxazole/trimethoprim, and acyclovir were administered prophylactically. The median age of the patients treated was

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[1977] Pegfilgrastim (6mg or 12mg) Mobilizes CD34⁺ Cells Similarly to Filgrastim (5mcg/kg/day) When Administered Following Chemotherapy in Patients with Non-Hodgkin's Lymphoma.

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Introduction: This phase 2, randomized, double-blind, dose-finding study assessed peripheral blood progenitor cell (PBPC) yields using 2 pegfilgrastim doses plus chemotherapy (CT) in patients (pts) with non-Hodgkin's lymphoma considered suitable for high-dose CT and autologous PBPC transplant.

Methods: Pts were given standard mobilizing CT (ICE: etoposide 100mg/m² days 1, 2, 3; carboplatin AUC 5 day 2; ifosfamide 5 g/m² day 2) followed by single-dose pegfilgrastim (6 or 12mg) or daily filgrastim (5 mcg/kg). Leukapheresis began

when the peripheral CD34⁺ count was $\geq 10/\text{mL}$ and white blood cell count was $\geq 2.5 \times 10^9/\text{L}$ and continued until a CD34⁺ yield of $\geq 5 \times 10^6/\text{kg}$ was obtained or a maximum of 5 aphereses were performed. Daily filgrastim was discontinued after the last apheresis. Pts with sufficient PBPC yields ($\geq 2 \times 10^6/\text{kg}$) then received high-dose CT (BEAM: BCNU 300mg/m², etoposide 800mg/m², cytarabine 1600mg/m², melphalan 140mg/m²) followed by PBPC transplantation and subsequent filgrastim until absolute neutrophil counts (ANC) recovered. Successful engraftment post-transplant was defined as 2 consecutive ANCs $> 0.5 \times 10^9/\text{L}$ and platelet counts of $> 20 \times 10^9/\text{L}$ independent of transfusions. Pts who did not have a collection were assigned a CD34⁺ yield of 0. Non-parametric descriptive statistics and Kaplan-Meier survival analyses were generated.

Results: A total of 92 pts were randomized, and 90 received study medication (29 pegfilgrastim 6mg or 12mg, 32 filgrastim). Baseline demographics and medical characteristics were balanced

across groups. A similar number of pts per group had at least one leukapheresis (21 pegfilgrastim 6mg; 20 pegfilgrastim 12mg; 25 filgrastim). The median (range) for mean harvest per leukapheresis was 1.18×10^6 CD34⁺ cells/kg (0.0 to 11.4) for pegfilgrastim 6mg, 1.44×10^6 (0.00 to 9.45) for pegfilgrastim 12mg, and 1.59×10^6 (0.00, 10.37) for filgrastim. Twenty (69%) pegfilgrastim 6mg, 17 (59%) pegfilgrastim 12mg, and 23 (72%) filgrastim pts had a harvest of $\geq 2 \times 10^6$ CD34⁺ cells/kg. Seventeen (85%) pegfilgrastim 6mg, 16 (94%) pegfilgrastim 12mg, and 18 (78%) filgrastim pts who achieved a yield of $\geq 2 \times 10^6$ CD34⁺ cells/kg reached this target yield in 1-2 leukaphereses. Median (range) number of days of filgrastim use in the collection phase was 12 (8 to 25). All pts who received a transplant on-study successfully engrafted except for 1 pt (pegfilgrastim 6mg) who died 4 days post-transplant. Median (95% CI) time to ANC recovery of at least $0.5 \times 10^9/\text{L}$ was 12 (10,13), 11 (10,13), and 11 (10,12) days for the

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