

Pegylated Filgrastim (PF) After High Dose Chemotherapy (HDC) and Autologous Stem Cell Transplant (ASCT)

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Background

PF (6 mg fixed dose) is equivalent to daily filgrastim (F) (5 mcg/kg/day for 14 days) after chemotherapy in decreasing the duration of neutropenia. Daily F (5 mcg/kg) started after HDC and ASCT leads to significant decrease in time to neutrophil engraftment (NE). The role of PF after HDC and ASCT is not known. We propose to study the role of PF given as a single fixed dose (6 mg) SQ on day +1 after stem cell (SC) infusion.

Methods

Fifteen patients (pts.) undergoing HDC and ASCT using peripheral blood SC for multiple myeloma or lymphoma have been enrolled in an ongoing study. SC were collected with peripheral blood pheresis after cyclophosphamide (3 g/sq.m) and daily F (10 mcg/kg). All pts. were eligible for HDC and ASCT as per institutional

criteria and consented. The conditioning regimens were high dose melphalan (200 mg/sq.m) for myeloma, and cyclophosphamide (7200 mg/sq.m), BCNU (400 mg/sq.m) and infusional etoposide (2400 mg/sq.m) for lymphoma. Pts. received antiinfective prophylaxis with acyclovir, levofloxacin and flucanazole starting day -1. Packed red blood cells (PRBC) and platelets were administered for a hematocrit and platelet count of less than 25% and 20,000 thousand/micro.L, respectively.

Results

There were no adverse events attributable to PF. All pts. engrafted neutrophils and platelets. The median time to NE was 10 days (range, 8-11). Incidence of febrile neutropenia was 67%, with a median duration of 2 days (range, 1-4). Twenty-three bacterial blood cultures were

obtained in 10 pts. for febrile episodes or a suspected line infection, with only 5 (in 5 pts.) being positive, all for coagulase negative staphylococcus. Antibacterials other than for prophylaxis was required in 60% (9/15) of patients. Antifungals other than for prophylaxis were not required. The median time to platelet engraftment was 17 days (range, 14-19). The median number of transfusions was 3 units of PRBC and 12 units of platelets. The median numbers of days with mucositis and total parenteral nutrition were 3 (range, 0-9) and 3 (range, 0-12), respectively.

Conclusions

PF at a fixed dose of 6 mg SQ administered on day +1 after HDC and ASCT appears to be equivalent to daily F. ■

Abstract # 7216

A Phase II Study of Pegfilgrastim to Support ACE 14 Chemotherapy

For the Treatment of Subjects With Small Cell Lung Cancer (SCLC; Extensive Disease)

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Background

Thatcher (JCO 2000; 18:395-404) showed that dose dense ACE with filgrastim allows delivery of "chemotherapy planned dose on time" (CPDOT) leading to improved survival in subjects with extensive SCLC. The aim of this study was to show that pegfilgrastim can also support ACE 14 CPDOT in this setting.

Methods

All 30 subjects received ACE (doxorubicin

40 mg/m² and cyclophosphamide 1000 mg/m² iv d1, etoposide 120 mg/m² iv d1 and 240 mg/m² PO d2-3) every 14 days for up to 6 cycles, with a single dose per cycle of pegfilgrastim 6 mg SC on d4. A cycle was considered "on time" if it started no more than 17 days after the start of the previous cycle, and "at planned dose" if ≥75% of drug was administered for each agent. For any given cycle, subjects were defined as having CPDOT if both criteria were

satisfied.

Results

27 subjects received pegfilgrastim and at least 1 cycle of ACE and 17 received all 6 cycles of ACE. Twenty subjects (74%) had no bone marrow involvement at baseline. The mean baseline ANC was 7.4x10⁹/L (range 3.0-23.3); over the study, mean ANC levels at the start of each cycle were ≥ 1.5x10⁹/L and were comparable to

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