

Pegfilgrastim Primary Prophylaxis vs. Current Practice Neutropenia Management in Elderly Breast Cancer Patients Receiving Chemotherapy

Aapro M, Schwenkglenks M, Lyman GH, et al. *Critical Reviews in Oncology/Hematology*. 2010; **74**:203-10.

Study Overview: Febrile neutropenia (FN) is associated with considerable morbidity and in-hospital mortality in adult breast cancer patients undergoing chemotherapy. FN and severe neutropenia commonly result in dose modifications and consequently reduced relative dose intensity (RDI), which has been shown to have a negative impact on survival in the adjuvant setting. Elderly patients (≥ 65 years) are particularly vulnerable to chemotherapy-induced FN and its complications, but derive the same benefits from chemotherapy as younger patients. Current EORTC guidelines therefore recommend support with granulocyte colony-stimulating factor (G-CSF) in elderly patients, in order to enable optimal chemotherapy delivery.

This analysis focuses on a subgroup of 254 patients ≥ 65 years from the NeuCuP (Neulasta[®] vs. current practice neutropenia management) study, an integrated analysis of individual patient data from 11 clinical trials and observational studies. The study compared pegfilgrastim primary prophylaxis (protocol-driven pegfilgrastim from cycle 1; PPP) with current practice neutropenia management (any current approach including daily G-CSF or pegfilgrastim in any cycle, or no G-CSF use; CP) in breast cancer patients receiving chemotherapy regimens with a moderately high (15-19%) to high ($\geq 20\%$) FN risk. The primary outcome measure was the incidence of FN across all cycles. The secondary outcome measures included the incidence of FN in cycle 1, the incidence of FN-related hospitalisation, dose modifications and haematological toxicity.

Key Findings:

- In the CP group, the **proportion of patients receiving no G-CSF was 73% in the first cycle** and 62% in cycle 6. Of the patients who received daily G-CSF, where number of doses was specified, five to seven doses per cycle were most common.
- **The incidence of FN was distinctly lower in patients receiving PPP** (6%; 95% confidence interval [CI]: 2, 10%) compared to patients in the CP group (24%; 95% CI: 16, 32%), particularly in cycle 1 (PPP 3% vs CP 15%).
- **The rate of FN-related hospitalisation was also lower with PPP** than with CP (PPP 5% vs CP 15% across all cycles).
- **The incidence of dose reductions $\geq 15\%$ in the PPP group was about half that in the CP group** (PPP 15% vs CP 29%). Patients receiving PPP also experienced numerically fewer dose delays > 3 days than patients in the CP group, but confidence intervals overlapped significantly.
- **Grade 3/4 neutropenia and leukopenia were more common in the CP group** than in patients receiving PPP.

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Conclusions: In this descriptive subgroup analysis in 254 elderly breast cancer patients receiving chemotherapy with a moderately high to high FN risk, PPP was associated with a lower incidence of FN and of dose reductions $\geq 15\%$. These results indicate that PPP provided effective prophylaxis against FN, and potentially increased the possibility of administering optimal chemotherapy in this particularly vulnerable patient group. In contrast current practice neutropenia management may not provide adequate protection.

<http://www.ncbi.nlm.nih.gov/pubmed/19748281>

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