

Differential efficacy of pegfilgrastim (Peg) in patients (pts) with breast cancer (BC) versus other cancer types for the prevention of docetaxel (Doc) chemotherapy-induced neutropenia (CIN).

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INTRODUCTION

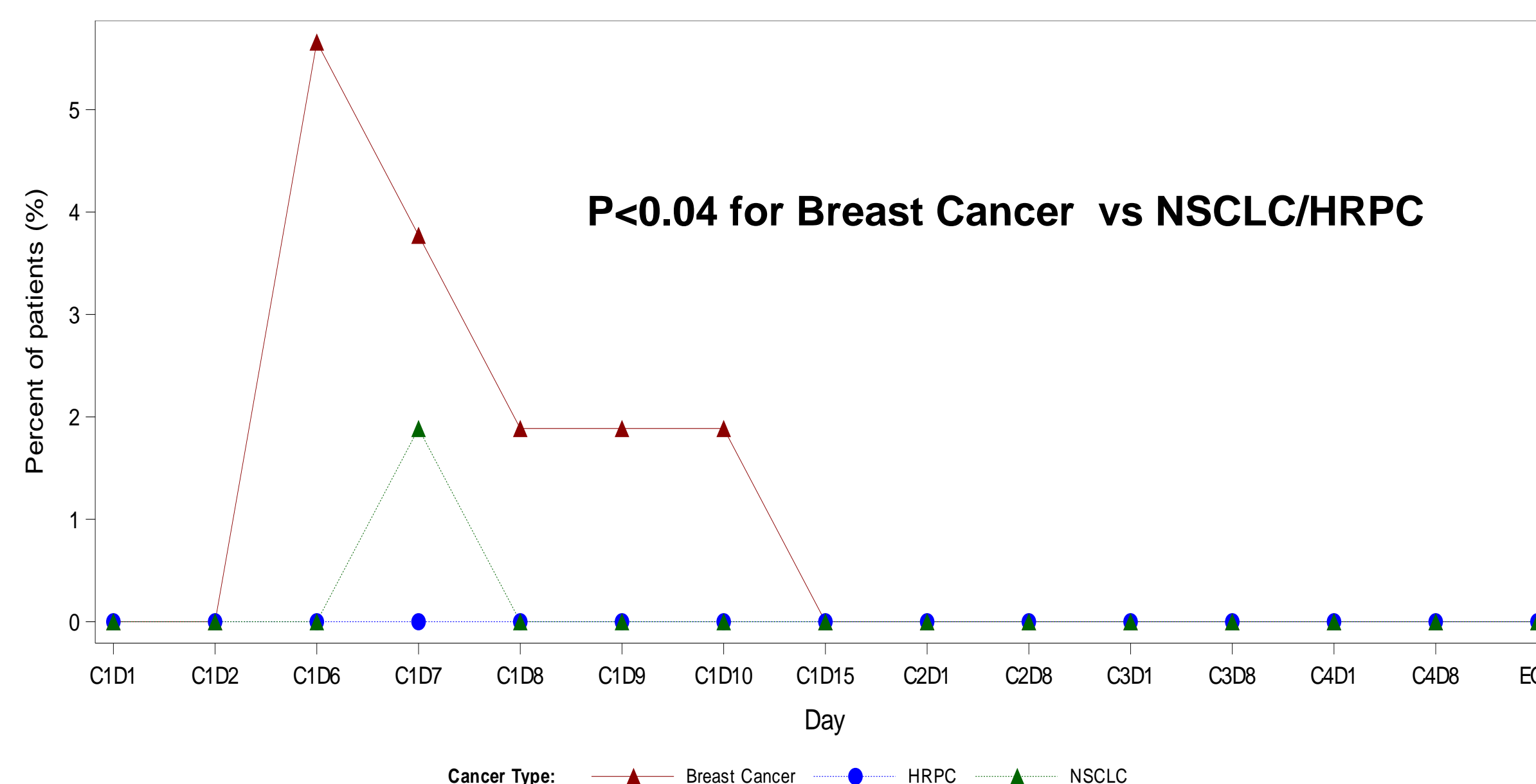
- G-CSF including Pegfilgrastim is standard of care for CIN prevention in Breast Cancer Patients
- Plinabulin is a novel non-GCSF small molecule agent and has dual activity:
 - Anti-cancer activity
 - Prevention of Chemotherapy-Induced-Neutropenia (CIN)
- Plinabulin is in development for the prevention of CIN.
- In the Phase 3 portion of Study BPI-2358-105 (NCT03102606) comparing single agent Plinabulin with single agent Pegfilgrastim.
- Here we compare the CIN efficacy of Pegfilgrastim between Breast Cancer patients and NSCLC/HRPC patients.

METHODS

- In Study 105, Breast Cancer, Lung (NSCLC) and Prostate cancer (HRPC) pts with at least 1 risk factor as per NCCN guidelines, received Docetaxel 75 mg/m².
- Patients were randomized to either Pegfilgrastim 6mg (n=53) or Plinabulin 40 mg (n=52). Here we only report on data from the Pegfilgrastim treatment arm.
- In the Pegfilgrastim arm, we enrolled:
 - N=27 Breast Cancer patients
 - N=26 NSCLC (N=17)/ HRPC patients (N=9)
- Patients had frequent blood draws in Cycle 1.
- Assessments:
 - Grade 4 Neutropenia frequency,
 - Duration of Severe Neutropenia (DSN)
 - Frequency of clinical sequelae of Neutropenia (Hospitalizations, Infections, Febrile Neutropenia, antibiotic use, chemotherapy dose reductions) in Cycle 1 to Cycle
- In addition, Grade 3/4, Duration of Severe/Moderate Neutropenia, ANC Nadir obtained from Phase 2 portion of Study 106 (NCT0329457), in Breast Cancer patients who were treated with TAC (Docetaxel 75, Doxorubicin 50 and Cyclophosphamide 500 mg/m²) is shown. Patients were randomized to either 6 mg Pegfilgrastim alone (n=22), or Pegfilgrastim 6mg + Plinabulin 20 mg/m² (n=16).

RESULTS

Frequency of Patients with Grade 4 Neutropenia with Breast Cancer, NSCLC or HRPC receiving Pegfilgrastim 6 mg after Docetaxel 75mg/m².



Numerically more Clinical Sequelae of CIN were reported for Breast Cancer compared to NSCLC/HRPC

Duration of Severe Neutropenia (DSN) in Breast Cancer Patients and NSCLC/HRPC patients

DSN	Breast Cancer	NSCLC/ HRPC
Mean (95% CI)	0.36 [0.28;0.49]*	0.076 [0.03;0.12]

* p<0.005 DSN Breast Cancer vs NSCLC/ HRPC

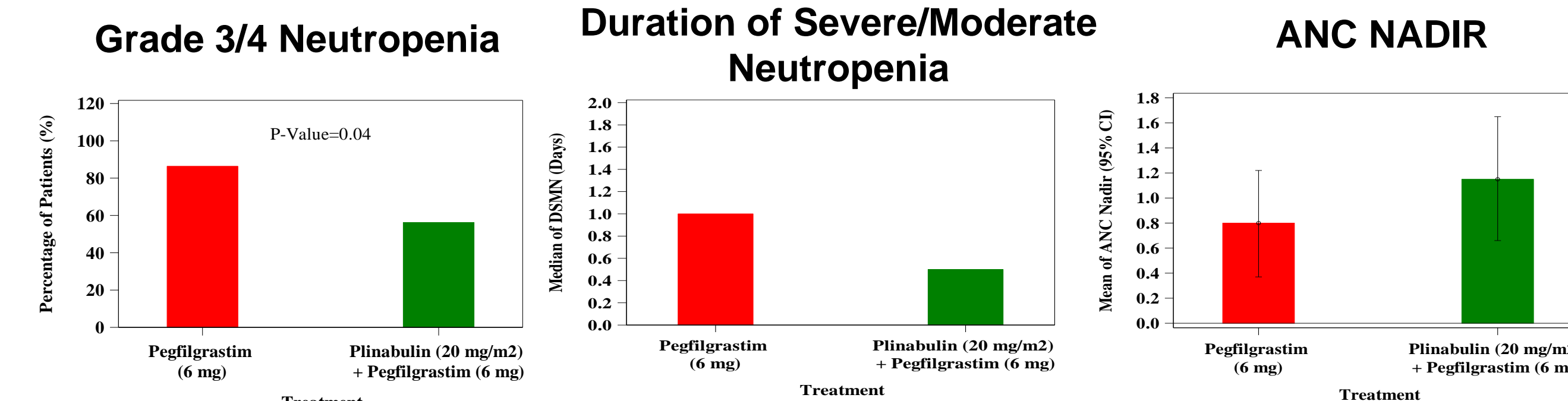
Number of Prior Chemotherapy Lines in Breast Cancer Patients with and without Grade 4 Neutropenia

Number of Prior Chemotherapy Lines	No Grade 4 Neutropenia with Pegfilgrastim	Yes Grade 4 Neutropenia with Pegfilgrastim
Mean (SD)	2.8 (2.55)*	3.2 (2.23)

* p=NS No Gr 4 vs Yes Gr 4 Neutropenia

RESULTS

Adding Plinabulin to Pegfilgrastim Provided Superior CIN Protection in Breast Cancer Patients after TAC Chemotherapy



CONCLUSIONS

- In Breast Cancer patients receiving Docetaxel 75 mg/m², Pegfilgrastim is less effective for CIN prevention compared to NSCLC/HRPC patients.
- The number of prior chemotherapy lines in patients with and without Grade 4 Neutropenia in Breast Cancer patients was comparable.
- The sub-optimal efficacy of Pegfilgrastim was due to its protection predominantly occurring in week 2 of the Cycle, leaving a significant number of patients unprotected in week 1 of the Cycle.
- The demonstrated effectiveness of Plinabulin in week 1 of the Cycle in Breast Cancer patients when combined with Pegfilgrastim could offer superior CIN protection vs Pegfilgrastim alone in Breast Cancer patients.

Contact

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