

Plinabulin and pegfilgrastim versus pegfilgrastim monotherapy after TAC: A comparison of efficacy, safety, relative dose intensity (RDI) and bone pain.

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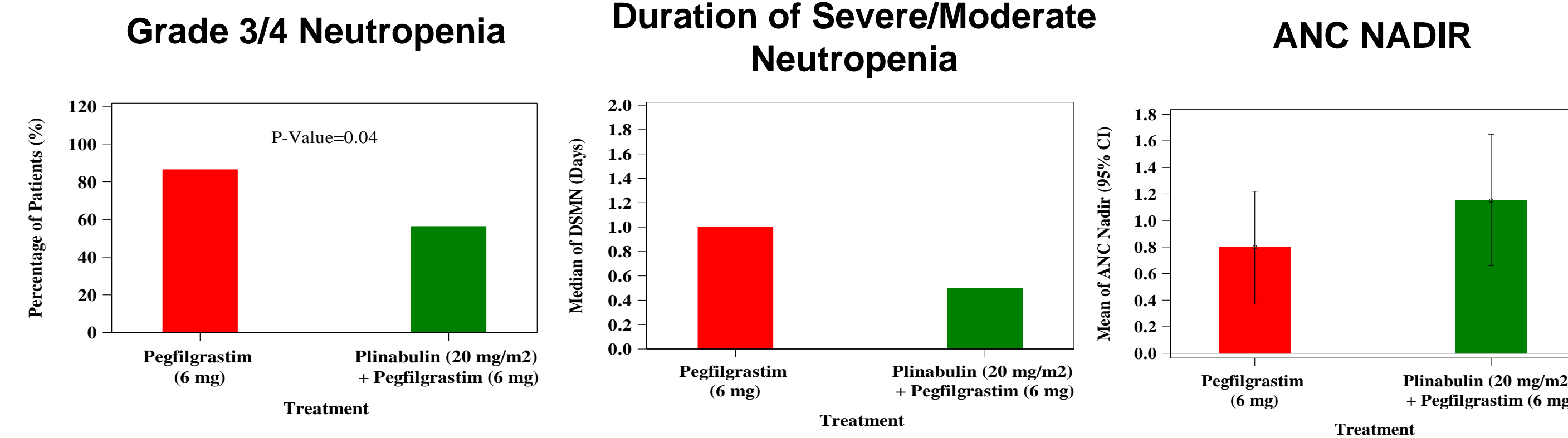
INTRODUCTION

- Plinabulin is a novel non-GCSF small molecule agent and has dual activity:
 - Anti-cancer activity
 - Prevention of Chemotherapy-Induced-Neutropenia (CIN)
- Plinabulin exerts CIN effects primarily in week 1 and Pegfilgrastim primarily in week 2 of the Cycle
 - This is the rationale for combining Plinabulin with Pegfilgrastim.
- In the Phase 2 portion of Study BPI-2358-106 (NCT0329457) we evaluated Plinabulin and Pegfilgrastim as single agent and in combination.
- Here we report on the Plinabulin/ Pegfilgrastim combination in comparison with Pegfilgrastim alone.
- Plinabulin has to date been administered to >600 patients with a favorable safety profile.

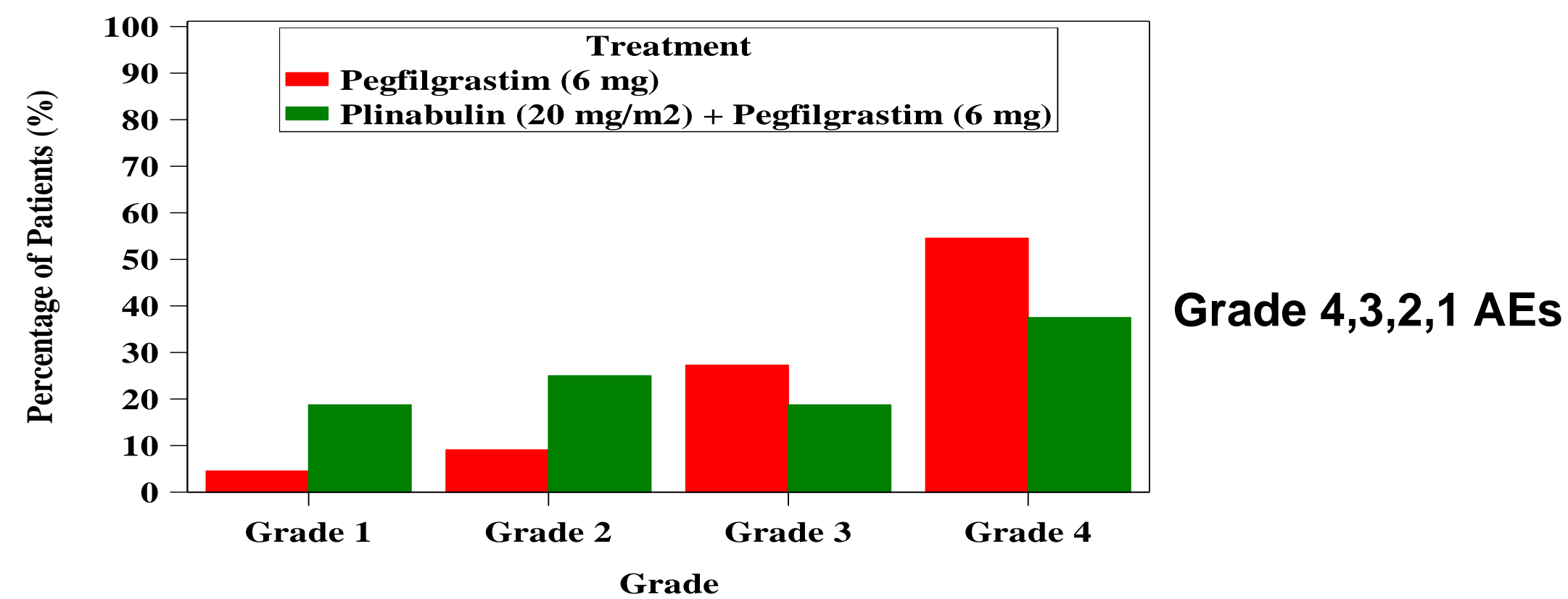
METHODS

- Phase 2 portion of Study 106 (NCT0329457), was conducted in Breast Cancer patients who were treated with TAC (Docetaxel 75, Doxorubicin 50 and Cyclophosphamide 500 mg/m²).
- Patients were randomized to either 6 mg Pegfilgrastim alone (n=22), or Pegfilgrastim 6mg + Plinabulin 20 mg/m² (n=16).
- Absolute neutrophil counts obtained on days 0, 1, 3, 6, 7, 8, 9, 10, 11, 12, 13, 15.
- Bone pain was assessed by a validated questionnaire
- Assessments:
 - Grade (Gr) 3/4 neutropenia frequency
 - Duration of Gr 3 and 4 neutropenia (DSMN)
 - Neutrophil nadir
 - Percentage of pts with RDI <85% was calculated
 - Adverse event rate (Grades 1-5) was calculated
 - Bone Pain

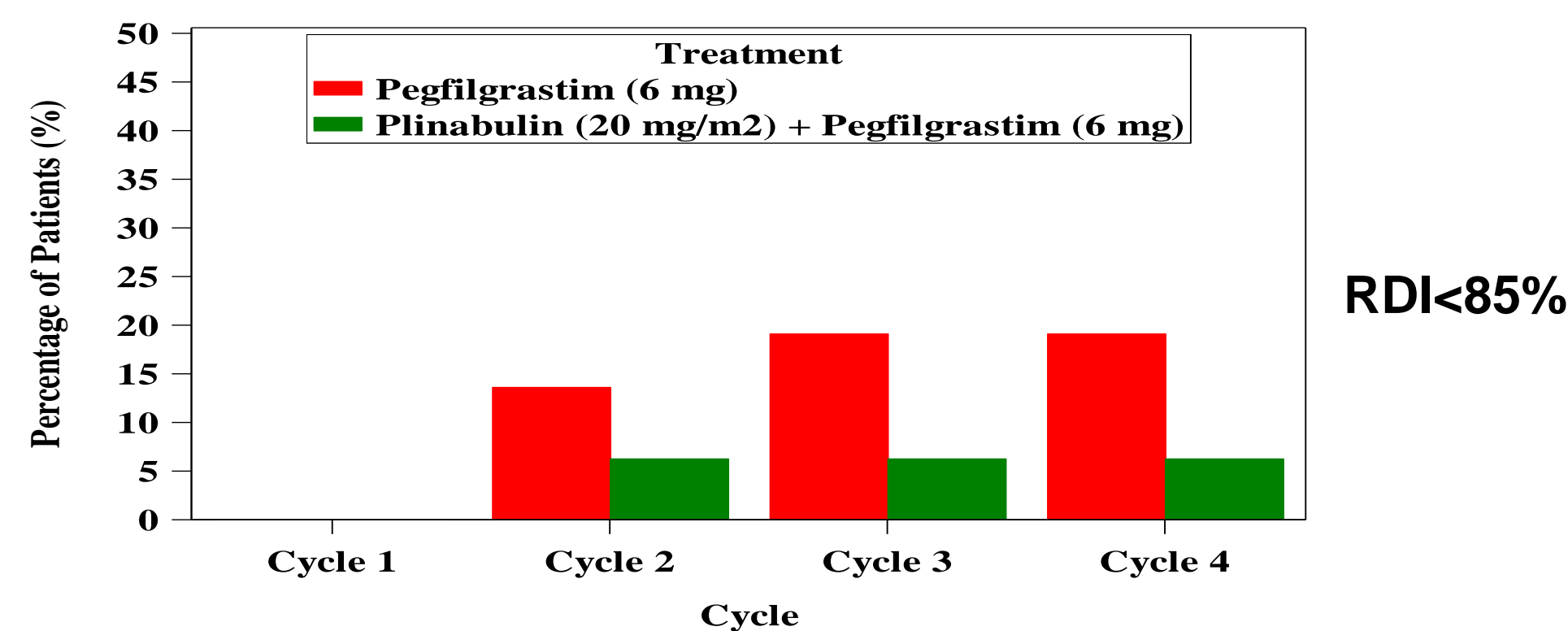
RESULTS



Shift to Lower AE Grade by Adding Plinabulin to Pegfilgrastim Compared to Pegfilgrastim Alone.

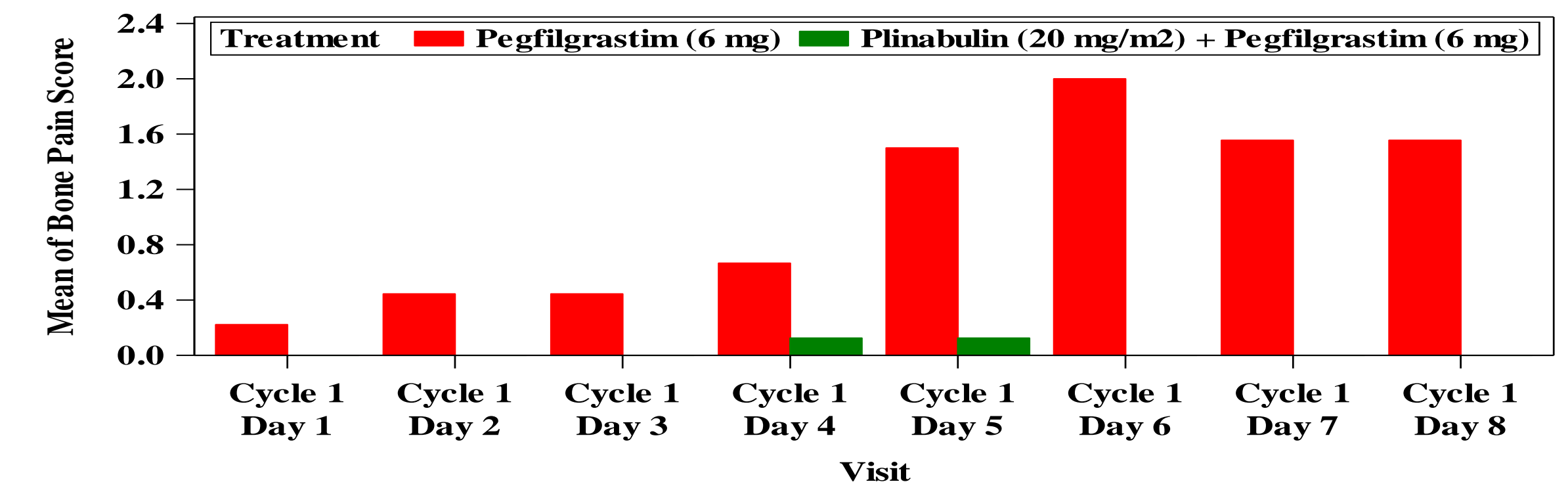


Avoidance of Chemotherapy Dose Reduction to RDI < 85% by Adding Plinabulin to Pegfilgrastim Compared to Pegfilgrastim Alone.



RESULTS

Adding Plinabulin to Pegfilgrastim almost Eradicated Bone-Pain caused by Pegfilgrastim.



CONCLUSIONS

- Compared to Pegfilgrastim alone, the Plinabulin / Pegfilgrastim combination has:
 - Superior prevention of CIN
 - Superior Safety
 - Superior RDI
 - Superior protection against Bone Pain
- A confirmatory global Phase 3 trial comparing the Plinabulin/Pegfilgrastim versus Pegfilgrastim alone is underway.

Contact

Disclosures: The first author received project support to his institution, and travel support from BeyondSpring during the conduct of the study. Dr Huang and Dr Mohanlal are employees of BeyondSpring Pharmaceuticals.

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