

TRIUMPH OF DARBEPOETIN ALFA IN NAVIGATING CHEMOTHERAPY-INDUCED ANEMIA: A COMPREHENSIVE REAL-WORLD STUDY FROM THE INDIAN SUBCONTINENT

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Background

Chemotherapy Induced Anemia (CIA), a common comorbidity in advanced solid tumor malignancies impacting the quality of life (QoL) leads to poor disease outcomes. Darbeipoetin alfa (DA; Cresp[®]) is approved for the management of CIA in a palliative setting. We retrospectively analysed real world effectiveness & tolerability of DA (Cresp[®]) in CIA in 523 patients from a single centre in India.

Materials & Methods

| Study setting: Narayana Superspeciality Hospital, Kolkata, India | | | Study time-period: 01/09/2017 to 31/08/2023 | | |
|--|---------------------------------|---|---|----------------------------|---|
| Patient Eligibility | | | | | |
| ≥ 18 yrs | Metastatic/advanced solid tumor | ≥2 myelosuppressive chemotherapy cycles | Palliative setting | Clinical/lab CIA diagnosis | ≥1 DA (Cresp [®] ; 200 µg, sc, biw) dose |

Outcomes

Effectiveness

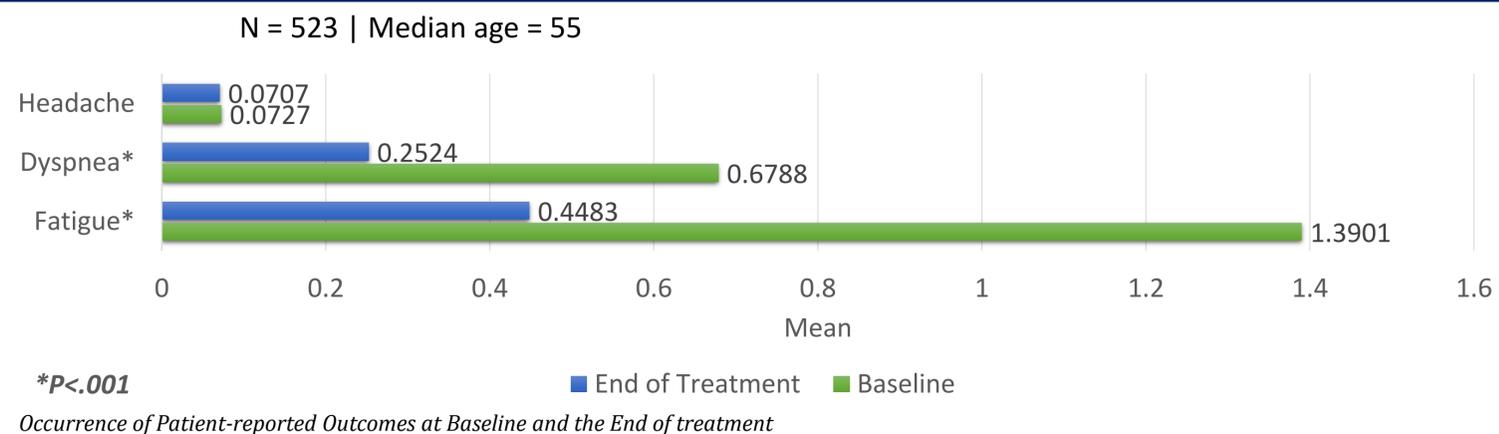
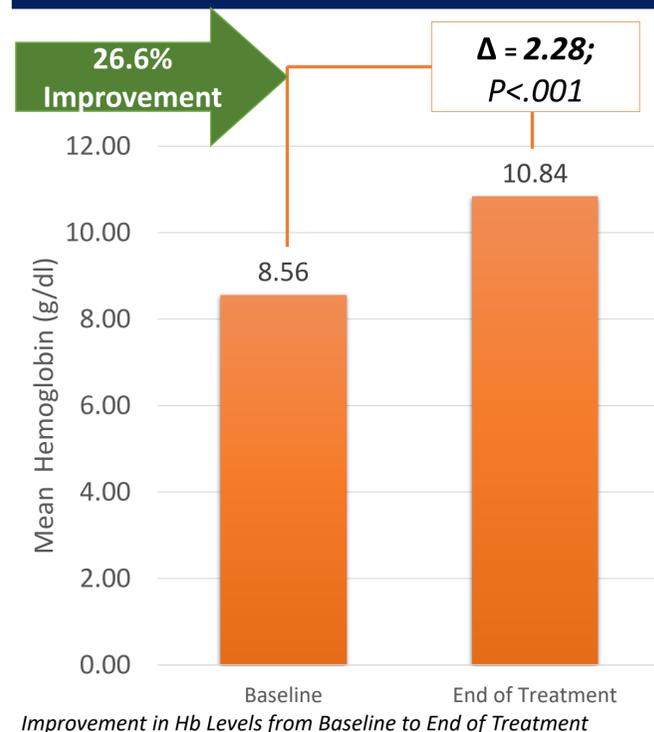
- Change in Hemoglobin (Hb) Levels
- Change in need for Blood Transfusion (BT)
- Change in Patient-reported outcomes (PRO)

Tolerability

Incidence of Treatment emergent adverse events (TEAE)

- Baseline Hb refers to Hb at time of CIA diagnosis.
- End of treatment Hb was the last recorded Hb before data cut-off.
- Baseline BT requirement was defined as per the NCCN guidelines.
- PROs for headache, fatigue, & dyspnea were evaluated using a scale rating each category from 0-3, with mean scores assessed at baseline and end of treatment.

Results



| Independence from BT | N | % |
|--|----------------|-----|
| Patients requiring BT at baseline | 50 | 9.6 |
| Patients receiving BT | 31 | 5.9 |
| DA (Cresp [®]) decreasing risk of BT | 19/50 (0.38) | 38 |
| DA (Cresp [®]) preventing BT | 28 / 50 (0.44) | 44 |

| TEAEs | N | % |
|----------------------------|----|------|
| Hypertension | 28 | 5.4% |
| Deep vein thrombosis | 15 | 2.9% |
| Arrhythmia | 4 | 0.8% |
| Congestive cardiac failure | 1 | 0.2% |
| Hypotension | 1 | 0.2% |

Mean Hb increment in Sub-groups*

| Cancer site | N (%) | Hb (Mean ± SD) |
|---------------------------------------|-------------|----------------|
| Gastrointestinal | 167 (31.93) | 2.38 ± 0.97 |
| Breast | 85 (16.25) | 2.29 ± 0.62 |
| Gynecological | 79 (15.11) | 2.19 ± 0.69 |
| Genitourinary | 58 (11.09) | 2.17 ± 0.72 |
| Lung | 55 (10.52) | 2.36 ± 0.52 |
| Head and neck squamous cell carcinoma | 33 (6.31) | 2.38 ± 0.74 |
| Others | 46 (8.80) | 2.00 ± 0.76 |
| Chemotherapy agents | | |
| Single | 133 (25.43) | 2.35 ± 0.76 |
| Multiple | 390 (74.57) | 2.25 ± 0.79 |
| Chemotherapy types | | |
| Taxane + Platinum | 120 (22.94) | 2.26 ± 0.67 |
| Gemcitabine + Platinum | 95 (18.16) | 2.30 ± 0.93 |
| Fluoropyrimidine - based | 86 (16.44) | 2.31 ± 0.85 |
| Single-Agent Taxane | 67 (12.81) | 2.39 ± 0.71 |
| Platinum + Other Agent/ Platinum Mono | 41 (7.84) | 2.12 ± 0.86 |
| Taxane + Other Agent | 33 (6.31) | 2.49 ± 0.64 |
| Pemetrexed/Methotrexate -based | 23 (4.40) | 2.49 ± 0.65 |
| Anthracycline - based | 17 (3.25) | 1.95 ± 0.88 |
| Others | 41 (7.84) | 2.03 ± 0.68 |
| Use of Platinum agents | | |
| Platinum | 354 (67.69) | 2.27 ± 0.82 |
| Non-Platinum | 169 (32.31) | 2.29 ± 0.71 |
| Response to therapy | | |
| Partial Response | 307 (58.70) | 2.66 ± 0.51 |
| Stable Disease | 159 (30.40) | 1.86 ± 0.82 |
| Progression of Disease | 57 (10.90) | 1.40 ± 0.59 |
| No. of doses of Darbeipoetin alfa | | |
| 4 Doses | 59 (11.28) | 1.61 ± 0.67 |
| 5 Doses | 22 (4.21) | 2.26 ± 0.54 |
| 6 Doses | 14 (2.68) | 2.54 ± 1.11 |
| 8 Doses | 428 (81.84) | 2.36 ± 0.76 |

*P < 0.001

Conclusion

This is the largest retrospective analysis of DA (Cresp[®]) in Indian patients to our knowledge. There was significant improvement in Hb levels across all sub-groups. Patients in partial response had greatest increment in Hb levels followed by stable disease, & least increment noted in those with disease progression. DA (Cresp[®]) decreased/prevented BT requirement, improved PROs, thereby enhancing QoL. There were no new safety signals apart from those already reported in literature.