

Usage and Clinical Outcomes of Erythropoietic Proteins for the Treatment of Chemotherapy-Induced Anemia: Clinical Evaluation of Anemia Response (CLEAR), a Multicenter, Retrospective Cohort Study

Authors Ralph Boccia, Stephen Davidson, Dianne Tomita, Larry Green, and Robert E. Smith

Origin of Study USA

Type of Study MULTICENTER, RETROSPECTIVE CHART REVIEW

Study Design Compare usage patterns and clinical outcomes of darbepoetin alfa and epoetin alfa treatment of chemotherapy-induced anemia in hospital outpatient and community oncology settings.

Sixty-five hospital and community-based oncology clinics nationwide provided the medical records.

Dosing and hemoglobin data were abstracted from consecutive medical charts of patients with chemotherapy-induced anemia who met eligibility criteria and received darbepoetin alfa or epoetin alfa therapy between August 1, 2002, and February 15, 2003.

Patients who were converted from one erythropoietic agent to the other during treatment were excluded from this analysis.

Change in hemoglobin was analyzed using descriptive statistics. The main analyses used an intent-to-treat (ITT) approach, in which missing hemoglobin values were imputed by carrying forward the last observed value. An additional sensitivity analysis was also conducted using available data only (ie, no imputation was used). For both, hemoglobin values within 28 days after a transfusion were excluded.

Patients Overall, 12 weeks of chart data from 3,123 patients were abstracted; 2,785 patients (1,444, darbepoetin alfa; 1,341, epoetin alfa) received only one erythropoietic agent.

Observations The most frequently administered doses were darbepoetin alfa 200 µg every 2 weeks (61%) and epoetin alfa 40,000 U weekly (72%).

For the subset of patients receiving the most common doses, the mean baseline hemoglobin concentration was identical, 10.3 ± 1.0 (SD) g/dL, in both treatment groups.

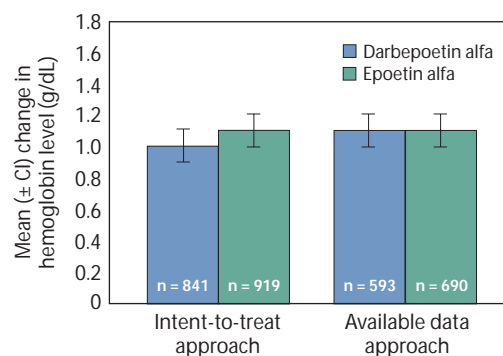
In these patients, the mean imputed hemoglobin change from baseline after 12 weeks of treatment in the ITT population was comparable for both the darbepoetin alfa and epoetin alfa groups: 1.0 (95% CI: 0.9–1.1) vs 1.1 (95% CI: 1.0–1.2), respectively.

The incidence of RBC transfusions was similar: 11% for darbepoetin alfa vs 12% for epoetin alfa.

Similar proportions of patients received increases in dose (22%, darbepoetin alfa; 23%, epoetin alfa) at a Kaplan-Meier median of 6 weeks for both groups.

Conclusions This retrospective analysis provides further evidence of the comparability, with respect to clinical outcomes, of darbepoetin alfa 200 µg administered every 2 weeks and epoetin alfa 40,000 U given once weekly for the treatment of chemotherapy-induced anemia in patients with cancer.

Change From Baseline Hemoglobin Level After 12 Weeks of Erythropoietic Therapy



Usage and Clinical Outcomes of Erythropoietic Proteins for the Treatment of Chemotherapy-Induced Anemia

Darbepoetin alfa 200 µg every 2 weeks has been adopted as the standard dose in the ambulatory patient setting and offers the benefit of less frequent administration, compared with that of epoetin alfa. Based on the current average wholesale price of these two drugs, this finding may also offer a cost-saving advantage for patients treated with darbepoetin alfa.

Discussion

The researchers drew data from 65 hospital and community-based oncology clinics nationwide to compare the early usage patterns and clinical outcomes of darbepoetin alfa (Aranesp) and epoetin alfa (Epoen, Procrit) for chemotherapy-induced anemia in the ambulatory oncology setting.

Dosing and hemoglobin data were abstracted from consecutive medical charts of patients with chemotherapy-induced anemia who met the eligibility criteria and received either darbepoetin alfa or epoetin alfa therapy from August 1, 2002, to February 15, 2003. Patients who were converted from one erythropoietic agent to the other during treatment were excluded from the analysis.

The clinics were chosen based on their ability to identify approximately 35 patients who were started on darbepoetin alfa in the period following the approval of the product in July 2002 and 35 patients who were started on epoetin alfa therapy in the same period. (If fewer than 35 patients were identified, the period was extended back 1 year from August 1, 2001, to February 15, 2003, until a sufficient number of patients were identified.)

Overall, 12 weeks of chart data from 3,123 patients were abstracted. Of these patients, 2,785 received only one erythropoietic agent, either darbepoetin alfa ($n = 1,444$) or epoetin alfa ($n = 1,341$). The most frequently administered doses were darbepoetin alfa 200 µg every 2 weeks and epoetin alfa 40,000 U weekly. For this subset of patients receiving the most common doses, the mean baseline hemoglobin concentration was identical, 10.3 g/dL, in both groups. In these patients, the mean hemoglobin change from baseline after 12 weeks of treatment was comparable for both treatment groups (1.0 g/dL for darbepoetin alfa vs 1.1 g/dL for epoetin alfa). Similar proportions of patients received increases in the dose of darbepoetin alfa (22%) and epoetin alfa (23%) at a Kaplan-Meier median of 6 weeks for both groups.

Key Points

- Darbepoetin alfa 200 µg every 2 weeks and epoetin alfa 40,000 U once weekly are comparable in terms of clinical outcomes for the treatment of chemotherapy-induced anemia.
- Because it requires less frequent administration, darbepoetin alfa therapy may also be more cost effective than epoetin alfa, given the current average wholesale price of these two drugs.

References

Boccia R, Davidson S, Tomita D, Green L, Smith RE. Usage and clinical outcomes of erythropoietic proteins for the treatment of chemotherapy-induced anemia (CIA): Clinical Evaluation of Anemia Response (CLEAR), a multicenter, retrospective cohort study. Poster presented at the 45th Annual Meeting of the American Society of Hematology; December 6–9, 2003; San Diego, Calif. Abstract 2761.