Advanced Colorectal Cancer

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Epoetin Alfa 80,000 U Every 2 Weeks vs. 40,000 U Weekly for Chemotherapy-Induced Anemia: Colorectal Cancer Patient Subset From a Randomized Clinical Study

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Background: A recent prospective study showed epoetin alfa **(**EPO) to be safe and effective for chemotherapy (CT)-induced anemia at an extended initiation dose of 80,000 units (U) every 2 weeks (Q2W).[1] Because anemia is a particularly common problem in colorectal cancer patients receiving CT, a retrospective analysis of this patient subset was undertaken.

Methods: Three hundred and ten (310) patients with non-myeloid malignancies with baseline hemoglobin (Hb) ≤11 g/dL and CT planned for ≥12 weeks were enrolled in a randomized, prospective, open-label, 13-week study.[1] Patients were assigned (1:1) to receive EPO 80,000 U Q2W or 40,000 U weekly (QW) subcutaneously. Drug was withheld for Hb >13 g/dL and dose was reduced for Hb >12 g/dL or rate of rise >1 g/dL in any 2-week period. For inadequate Hb response, 80,000 U Q2W patients were

switched to 40,000 U QW, and 40,000 U QW patients were increased to 60,000 U QW. The primary analysis was a comparison of the mean Hb change from baseline to end of study. The 42 patients with colorectal cancer enrolled in the prospective study were included in this retrospective subset analysis.

Results: Forty-two (42) patients (safety and modified intent-to-treat populations; 24 Q2W, 18 QW) received ≥1 EPO dose and had ≥1 post-baseline Hb measurement. Approximately 50% of patients in each group received dose-dense CT. Baseline characteristics were comparable: 63% of Q2W and 50% of QW patients were female; mean age 63 years Q2W, 65 years QW; mean baseline Hb 10.3 g/dL Q2W, 10.1 g/dL QW. Mean Hb change from baseline to end of study was 1.29±1.15 g/dL for Q2W vs. 1.24±1.29 g/dL for QW (difference -0.12, 95% confidence interval [CI], -0.8, 0.6). Median time to achieve Hb of 11 g/dL was 15 days for Q2W vs. 36 days for QW. No Q2W patient received packed red blood cell transfusion in weeks 5-13 vs. 2 (14%) in QW. Fewer Q2W vs. QW patients required dose withholds (38% vs. 44%) or reductions (38% vs. 50%). Four percent (4%) of Q2W patients were switched to QW dosing and 39% of QW patients required a dose increase to 60,000 U QW. Eight percent (8%) of Q2W patients and 6% of QW patients experienced a clinically relevant thrombotic vascular event. No Q2W patients and 3 (17%) QW patients died during the study period (1 each cerebrovascular accident, bowel obstruction, and cardiac arrest, all unrelated to EPO).

Conclusions: As was previously shown in the overall study population, EPO 80,000 U Q2W was safe and effective and resulted in comparable hematopoietic outcomes as EPO 40,000 U QW in this subset of anemic colorectal cancer patients receiving CT.

Reference

1. Henry DH, Gordan LN, Charu V, et al: Randomized, open-label comparison of epoetin alfa extended dosing (80 000 U Q2W) vs weekly dosing (40 000 U QW) in patients with chemotherapy-induced anemia. *Curr Med Res Opin* 22:1403-1413, 2006