ANNA
AMERICAN NEPHROLOGY NURSES' ASSOCIATION
ANNA'S 43RD NATIONAL SYMPOSIUM
APRIL 29-MAY 2, 2012
WALT DISNEY WORLD DOLPHIN, ORLANDO, FL

Hemoglobin (Hb) Variability During Peginesatide Versus Epoetin Treatment in Patients on Dialysis

Lori McFadden RN, BSN, CCRP[1], Paula LaFleur RN, BSN, CCRP[1], Carol Francisco PhD[2], Alex Yang, MD[2], Martha Mayo, PharmD[2]
[1]St. Clair Specialty Physicians, Detroit, MI; [2]Affymax, Inc., Palo Alto, CA

Background: The current practice of dialysis anemia management consumes significant nursing time with numerous administrative tasks such as Hb checks, dose adjustments, and documentation. A time and motion study suggests that once monthly erythropoiesis-stimulating agent (ESA) administration would reduce time devoted to anemia management and may free more time for other valuable care activities such as patient education (Schiller B, et al. *Hemodial Int.* 2008;12:441-9). Peginesatide is a synthetic, PEGylated, investigational, peptide-based ESA that stimulates the erythropoietin receptor. This analysis compared Hb variability in patients treated with once-monthly peginesatide compared with 1-3 times weekly epoetin alfa/beta.

Methods: Two randomized, open-label phase 3 trials were conducted to assess the safety and efficacy of peginesatide compared with epoetin (EMERALD 1 and 2); 1608 established patients on in-center hemodialysis were enrolled. Hb variability was measured using two methods: the standard deviation (SD) of Hb levels within patients and median of the absolute deviation (MAD) from the median within-patient Hb level. A composite safety endpoint (CSE) was evaluated consisting of 6 events: all causes of death, stroke, myocardial infarction, and serious adverse events of congestive heart failure, unstable angina, and arrhythmia.

Results: Hb variability was similar for the peginesatide and epoetin groups using both SD (median = 0.51 vs 0.48) and MAD (median = 0.44 for both) methods. Fewer patients in the peginesatide than epoetin group (47% vs 68%) had dose adjustments (>20% change from previous dose; weeks 29-36). The frequency of CSE events during the studies was similar for both groups (23% vs 24%).

Conclusions: Hb variability was similar for peginesatide and epoetin while fewer patients in the peginesatide group had dose adjustments. Similar rates of cardiovascular events were reported for peginesatide and epoetin in this population of hemodialysis patients.

Abstract selected for presentation at ANNA's 43rd National Symposium, Orlando, FL, 2012