

HEMOGLOBIN (Hb) VARIABILITY IN SUBJECTS WITH CHRONIC KIDNEY DISEASE (CKD) NOT ON DIALYSIS (NOD): AN ANALYSIS OF DARBEPOETIN ALFA CLINICAL TRIAL DATA

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Hb variability (HbV) has been described in observational studies of CKD dialysis patients (pts), and may contribute to inefficient anemia management in CKD pts treated with ESAs. However, HbV in NOD CKD pts has not been well described. Here, we characterize HbV in NOD CKD pts using data from controlled clinical trials where ESA therapy was closely managed per study protocol.

Four trials where NOD CKD pts were treated with darbepoetin alfa to maintain Hb levels within a 2 g/dL range (10-12 g/dL for Studies 1 & 2; 11-13 g/dL for Studies 3 & 4) were used in this analysis. HbV was characterized using 3 methods: intra-pt Hb standard deviation (SD); proportion (Pr) of pt's Hb measurements within the study's Hb target range; and an ordinal categorization of the pt's Hb level fluctuation.

A total of 877 pts were included in this analysis. Patient characteristics and HbV are shown below.

| Baseline Characteristics / Variability Definition | Study 1 N = 94 | Study 2 N = 111 | Study 3 N = 149 | Study 4 N = 523 |
|---|-------------------|--------------------|--------------------|--------------------|
| Hb level, mean (SD) g/dL | 11.1 (0.6) | 11.4 (0.9) | 11.9 (0.6) | 11.9 (0.6) |
| eGFR, mean (SD) mL/min/1.73m ² | 22.5 (8.0) | 25.4 (9.6) | 28.5 (10.6) | 29.2 (10.5) |
| Intra-subject Hb SD, Mean (SD) | 0.6 (0.2) | 0.9 (0.4) | 0.7 (0.3) | 0.7 (0.3) |
| Pr of Hb in target, Mean (SD) | 0.8 (0.2) | 0.7 (0.2) | 0.7 (0.2) | 0.7 (0.3) |
| Achieved Hb measurement, n (%) | | | | |
| - Always below, or always within, or always above target | 16 (17.0) | 12 (10.8) | 17 (11.4) | 110 (21.0) |
| - Below and within, or above and within target | 62 (66.0) | 81 (73.0) | 110 (73.8) | 339 (64.8) |
| - Below, within, and above target | 16 (17.0) | 18 (16.2) | 22 (14.8) | 74 (14.1) |

These results indicate that while NOD CKD patients treated by an ESA protocol can maintain a target Hb 70-80% of the time, most experience excursions. Different methods were used in this analysis; the application of these methods and the interpretation of the results should depend on the purpose of the analysis.