

Variability in Hemoglobin Levels in Hemodialysis Patients in the Current Era

David T. Gilbertson¹, Yan Hu¹, Yi Peng¹, Sarb Shergill², and Bradley J. Maroni²

¹Chronic Disease Research Group, Minneapolis, MN, ²Akebia Therapeutics, Inc., Cambridge, MA

Introduction

- Hemoglobin (Hb) variability in dialysis patients has been characterized using a number of methods.
- Most prior analyses were conducted before the 2011 change in CMS reimbursement policy (Jan) and revised erythropoietin-stimulating agent (ESA) labels (July).
- Therefore, Hb variability (and patient demographics) from recent data were compared to results obtained before implementation of these policy changes.
- We also explored anemia management (including ESAs, IV iron, and red blood cell transfusions) across the Hb variability groups.

Methods

- The study population consisted of maintenance HD patients as of October 1, 2012, with Medicare as primary payer during the baseline period (April 1 - September 30, 2012).
- Monthly Hb values were categorized as low (L), intermediate (I), or high (H), where L and H were based on monthly Hb values below or above the 25th and 75th percentiles, respectively.
- Hb variability was then classified into six groups based on the lowest and highest category during the six month observation period (LL, consistently low; II, consistently intermediate; HH, consistently high; LI, low-intermediate; IH, intermediate-high; LH, low-high)(see Figure 1).

- ESA use, iron use, red blood cell transfusion and comorbid conditions were also assessed.

Figure 1. Idealized example of Hb variability groups

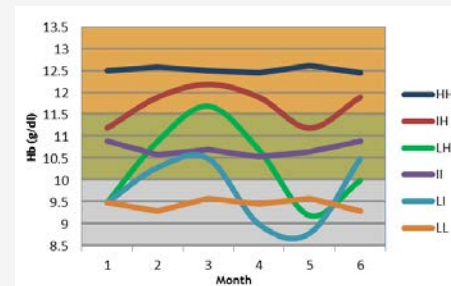


Table 1 Hb intermediate range in 2004 vs. 2012 data

| Study year | Hb intermediate range (g/dl) |
|------------|------------------------------|
| 2004 | 11 - 12.5 |
| 2012 | 10 - 11.5 |

Figure 2. The percentage of patients in each Hb variability group in 2004 and in 2012

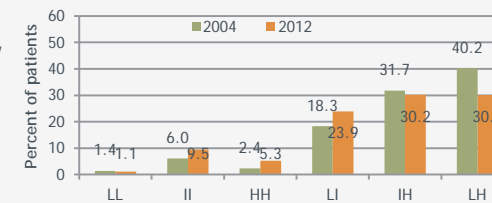


Table 2. Distribution of demographics and comorbidity by Hb variability groups in 2012

| Variable | Overall | LL | II | HH | LI | IH | LH |
|--|------------|------------|------------|------------|------------|------------|------------|
| Total patients, N | 200,728 | 2,200 | 18,999 | 10,552 | 48,029 | 60,525 | 60,423 |
| Age ^a , mean(SD), years | 63.0(14.7) | 58.2(15.7) | 65.2(14.2) | 57.8(13.7) | 63.3(14.8) | 63.4(14.6) | 62.9(15.0) |
| Sex, % | | | | | | | |
| Female | 46.0 | 44.9 | 47.5 | 22.7 | 49.7 | 43.2 | 49.6 |
| Male | 54.0 | 55.1 | 52.5 | 77.3 | 50.3 | 56.8 | 50.4 |
| Race, % | | | | | | | |
| White | 53.1 | 45.8 | 54.9 | 53.8 | 51.6 | 55.0 | 52.0 |
| Black | 40.3 | 48.8 | 37.6 | 40.3 | 41.3 | 38.9 | 41.4 |
| Other | 6.6 | 5.4 | 7.5 | 5.9 | 7.0 | 6.1 | 6.6 |
| Dialysis duration ^a , mean(SD), years | 5.6(5.1) | 5.9(5.5) | 5.4(4.7) | 7.1(5.8) | 5.6(4.9) | 5.5(5.1) | 5.4(5.1) |
| Primary cause of ESRD, % | | | | | | | |
| Diabetes | 44.6 | 35.9 | 46.5 | 36.2 | 45.3 | 44.7 | 45.2 |
| Hypertension | 29.9 | 27.0 | 30.1 | 30.3 | 29.3 | 30.4 | 29.8 |
| GN | 9.3 | 11.1 | 8.5 | 13.4 | 9.1 | 9.4 | 8.9 |
| Other cause | 16.2 | 25.9 | 14.9 | 20.0 | 16.3 | 15.5 | 16.1 |
| Hospitalized, % | 37.0 | 62.2 | 22.9 | 18.9 | 44.6 | 28.1 | 46.5 |
| Comorbidity, % | | | | | | | |
| ASHD | 41.9 | 46.4 | 37.8 | 30.1 | 44.5 | 39.3 | 45.6 |
| CHF | 43.2 | 54.0 | 38.8 | 31.1 | 47.0 | 39.7 | 46.9 |
| CVA/TIA | 17.8 | 17.2 | 14.8 | 10.9 | 18.9 | 16.1 | 20.6 |
| PVD | 45.3 | 50.2 | 41.4 | 34.6 | 47.5 | 42.8 | 49.0 |
| Other cardiac disease | 69.0 | 75.9 | 67.4 | 62.1 | 71.3 | 67.0 | 70.8 |
| COPD | 18.7 | 27.6 | 14.5 | 12.8 | 20.8 | 16.6 | 21.3 |
| GI bleeding | 6.0 | 18.5 | 2.8 | 2.1 | 8.0 | 3.5 | 8.0 |
| Liver disease | 6.0 | 11.9 | 4.9 | 5.3 | 6.1 | 5.8 | 6.3 |
| Dysrhythmia | 31.8 | 40.0 | 27.8 | 23.8 | 34.6 | 29.1 | 34.6 |
| Cancer | 9.1 | 16.2 | 8.7 | 5.1 | 10.7 | 7.9 | 9.7 |
| Diabetes | 63.7 | 59.1 | 64.7 | 52.2 | 65.3 | 62.9 | 65.1 |

SD, standard deviation; ESRD, End-stage renal disease; ^aOn index date (October 1, 2012). ^bAssessed from Medicare claims during the baseline period.

Figure 3. Total EPO monthly dose among users by Hb variability groups

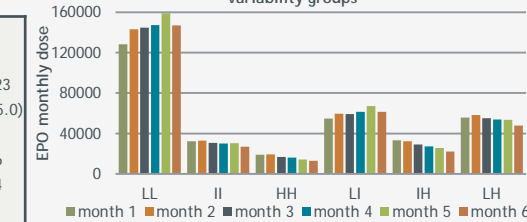


Figure 4. The percentage of total months of IV iron use by Hb variability groups

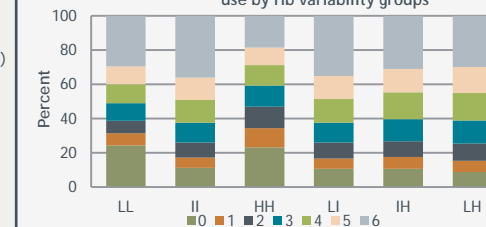
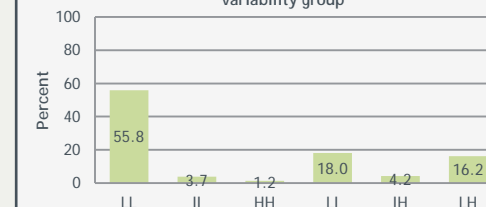


Figure 5. The percentage of transfusions by Hb variability group



Results

- Approximately 200K HD patients were included in this analysis.
- The 25th and 75th percentiles of Hb values in the 2012 data were 10.2 (rounded to 10) and 11.5 (illustrated in Figure 1 by shading). Corresponding 2004 values were 11 and 12.5 g/dL.

- Similar percentages of patients were observed in 2004 and 2012 in the LL and IH categories. In 2012 (compared to 2004) a smaller percentage was LH, whereas higher percentages were LI and II (Figure 2).
- Compared with the overall 2012 cohort, II patients were older (mean=65.2 yr.), and LL and HH patients were younger (mean=58.2 and 57.8) and had longer dialysis durations (mean=5.9 and 7.1). More LL patients were black (48.8%), and had the highest percentage of hospitalizations (62.2%); also, comorbid conditions were relatively worse in this group.
- Patients in the LL or LI Hb categories received the highest ESA doses and transfusions, whereas patients who were consistently II or HH received lower ESA doses and fewer transfusions (Fig. 3 and 5).
- Patients in the HH Hb category were less likely to receive iron; more than one-third of patients with consistently II, or LI Hb received monthly iron (Figure 4).

Conclusions

- While Hb levels have decreased since implementation of the 2011 policy changes, Hb variability remains.
- The lower percentage of patients in the LH group is consistent with narrowing of the overall Hb distribution.
- Demographics, comorbidities and anemia management in Hb variability groups vary, especially in groups LL and II.
- Further studies are needed to assess the association of Hb variability with outcomes in the current era.



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