

Variability in Hemoglobin Levels in Hemodialysis Patients in the Current Era

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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 (January) and revised erythropoietin-stimulating agent (ESA) labels (July).
- Therefore, Hb variability (and patient demographics) from recent data were compared with 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 hemodialysis 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 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 6-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 transfusions, and comorbid conditions were also assessed.

Figure 1. Idealized example of Hb variability groups

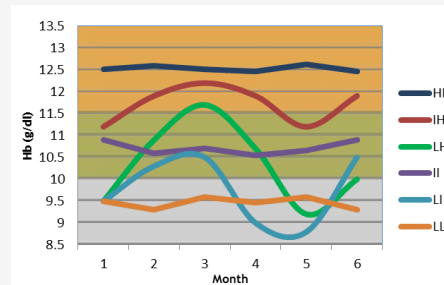
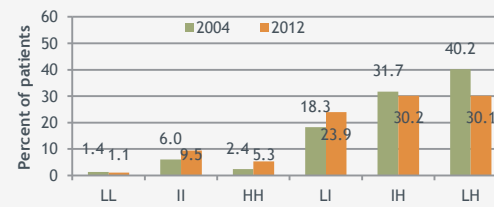


Table 1. Hb intermediate range in 2004 vs. 2012 data

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



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, ^a %							
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, ^a %							
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, ^b %	37.0	62.2	22.9	18.9	44.6	28.1	46.5
Comorbidity, ^b %							
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

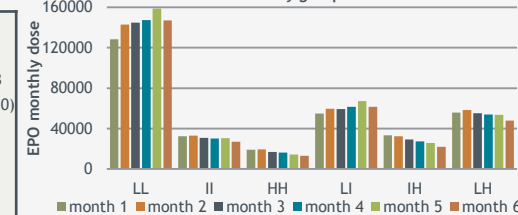


Figure 4. The percentage of total months of IV iron use by Hb variability groups

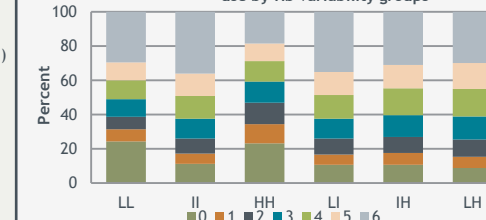
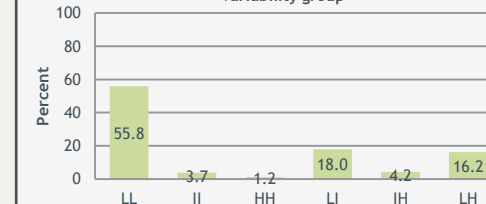


Figure 5. The percentage of transfusions by Hb variability group



Results

- Approximately 200K hemodialysis 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 with 2004) a smaller percentage were LH, and higher percentages were LI and II (Figure 2).
- Compared with the overall 2012 cohort, II patients were older (mean age 65.2 years), and LL and HH patients were younger (mean 58.2 and 57.8 years) and had longer dialysis durations (mean 5.9 and 7.1 years). More LL patients were black (48.8%), and the highest percentage were hospitalized (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 the most transfusions; patients who were consistently II or HH received lower ESA doses and fewer transfusions (Figures 3 and 5).
- Patients in the HH Hb category were less likely to receive iron; more than one-third of patients who were consistently II or LI 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, comorbid conditions, 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.



Funded by a research contract from Akebia Therapeutics, Inc.

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