Developing an HbA₁c-Based Equation to Estimate Blood Glucose in Maintenance Hemodialysis Patients

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OBJECTIVE—Hemoglobin A₁c (HbA₁c) has been widely used as a clinically important assessment tool for outcome analyses related to glycemic control. However, because of special conditions in dialysis patients, including the uremic milieu, there is no HbA₁c blood glucose (BG) equation specific for patients on dialysis. In this study, we sought to develop HbA₁c-BG equation models for hemodialysis patients.

RESEARCH DESIGN AND METHODS—We examined associations between HbA₁c and random serum BG over time in a contemporary cohort of diabetic patients with hemodialysis treated in DaVita dialysis clinics. We identified 11,986 patients (63 ± 12 years old and 49% male) with 69,764 paired measurements of HbA₁c and BG over the course of 5 years (2001–2006). Bootstrapping method was used to estimate average BG and corresponding HbA₁c levels. The association was adjusted by patient factors using linear regression.

RESULTS—Linear regression analyses yielded the following three regression equations: BG = $59.2 + 29.4 \times HbA_{1c} - 20.8 \times Alb$ ($R^2 = 0.483$); BG = $104.8 + 29.7 \times HbA_{1c} - 18.4 \times Alb - 4.7 \times Hb$ ($R^2 = 0.486$); and BG = $82.9 + 30.7 \times HbA_{1c} - 16.5 \times Alb - 5.4 \times Hb + 0.3 \times age + race$ ($R^2 = 0.491$). All our models showed stronger association than previous equation models ($R^2 = 0.468$ in the Diabetes Control and Complications Trial and A1c-Derived Average Glucose equations).

CONCLUSIONS—The association between HbA₁c and BG in hemodialysis patients is different than that of patients with normal kidney function. Our analysis suggests that equations including serum albumin or hemoglobin are better for hemodialysis patients.

H emoglobin A1c (HbA₁c) has been widely used as a clinically important assessment tool for outcome analyses related to glycemic control. Numerous studies have documented that HbA₁c is highly correlated with a patient's directly measured blood glucose (BG) levels averaged over time. There are some equations showing a good correlation between HbA₁c and average BG (AG) levels (the Diabetes Control and Complications Trial [DCCT] formula: AG = $35.6 \times HbA_{1c} - 77.3$; and the A1c-Derived Average Glucose [ADAG] study: AG = $28.7 \times HbA_{1c} - 46.7$) (1,2). The recommendation of ADAG group implies that HbA₁c is a reliable substitute for mean BG and, except for analytic variation, the only important factor determining HbA₁c is the preceding mean BG.

Glycation rate is determined by temperature, pH, hemoglobin (Hb) concentration, BG concentration, and length of exposure to glucose (3). Because the Hb concentration and pH of dialysis patients can be significantly abnormal, the correlation between HbA₁c and AG levels in dialysis patients is considered different from that of normal patients. Furthermore, shortened erythrocyte life span and accelerated erythropoesis because of routine use of erythropoietin could affect HbA₁c levels in dialysis patients. HbA₁c was found to underestimate glucose measurements in diabetic patients on dialysis compared with glycated albumin (4–6). Unfortunately, there has been no HbA₁c-AG equation specific for hemodialysis (HD) patients, despite the increasing number of diabetic patients on dialysis. In this study, we sought to develop HbA₁c-AG equation models for HD patients.

RESEARCH DESIGN AND METHODS

Database creation
The data were obtained from DaVita, the second largest dialysis care provider in the United States, with ~500 dialysis centers and 40,000 patients across the country. The creation of the national DaVita dialysis patient cohort has been described previously (7–12). A 60-month prevalent cohort (July 2001–June 2006) of DaVita maintenance HD patients was studied. Demographic data and details of medical history were collected, with information on age, gender, race, and presence of diabetes. The study conformed to Declaration of Helsinki and Good Clinical Practice Guidelines.

Laboratory measures
Blood samples were drawn using uniform techniques in all of the DaVita dialysis clinics and were transported to the DaVita Laboratory in Deland, Florida, typically within 24 h. All laboratory values were

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measured by automated and standardized methods in the DaVita Laboratory. Most laboratory values were measured monthly, including serum urea nitrogen, creatinine, serum albumin (Alb), BG, calcium, phosphate, and bicarbonate. Hb was measured at least monthly in essentially all patients. HbA_{1c} was measured at least quarterly. All these variables were measured before HD, with the exception of postdialysis serum urea nitrogen.

Statistical methods

Data were summarized using proportions, means (±SD) as appropriate. Categorical variables were analyzed with the χ^2 test or Fisher exact test as appropriate, and continuous variables were compared using t test, Mann-Whitney U test, Kruskal-Wallis H test, or ANOVA, as appropriate. Patients receiving dialysis for <90 days, those without diabetes, those with missing values of Alb, glucose, Hb, or HbA_{1c}, and those who were tested for values less than three times were excluded from this analysis. Laboratory values in this data set were refined using limits as follows: albumin, 1.0–5.0 g/dL; BG, 30–500 mg/dL; Hb, 3–20 g/dL; and HbA_{1c} 1–12 mg/dL, respectively. All repeated measures of every relevant variable for each patient within each calendar quarter or 13 weeks were averaged to obtain one quarterly

mean value for that given variable. Averaged HbA_{1c} values and BG values were compared using regression models with and without adjustment for Hb, Alb, patient age, gender, or race or ethnicity. In addition to linear models, quadratic, root, log, and exponential regression models also were applied to estimate the relationship between averaged HbA_{1c} and BG. Bootstrapping method also was used to estimate AG and corresponding HbA_{1c} for more reliable estimates. One thousand resampling procedures with replacement were selected to approximate the sampling distribution of statistics of interest. R^2 and root mean square error were used to compare the correlations between the simple and multivariate regression models. After identifying the best models, we applied them to gender-based and race-based categories to compare the accuracy of the models in each subgroup. The DCCT and the ADAG formulas were used as control formulas.

RESULTS

Equation model creation

Baseline characteristics are shown in Table 1. The mean age was 63 ± 12 years, which was slightly higher in Asians (66 ± 11 years) than in African Americans (62 ± 12 years). Most patients were non-Hispanic

white (33%), African American (34%), and Hispanic (21%), with relatively few Asian and other races, including Pacific Islander and Native Americans. The mean dialysis vintage was 2.9 ± 2.5 years. Eighty percent of patients in this study had type 2 diabetes mellitus. Most characteristics were similar in males and females.

The relationship between the average HbA_{1c} and the AG ($n = 11,986$) is shown in Fig. 1 and Table 2. The scatter plot suggests that there is a linear relationship between HbA_{1c} and BG, which is the same as the relationship previously reported in nondialysis populations (1,2). Rohlfing et al. (1) also reported that afternoon and evening BG showed higher correlations with HbA_{1c} than did the morning values. Our analysis also showed that the relationship between HbA_{1c} and BG among patients in the afternoon or evening shift ($R^2 = 0.494$) was better than during the morning ($R^2 = 0.477$) (see Supplementary Fig. 1). Next, we compared several equation models with and without adjustment for confounding factors. As shown in Table 2, the equation improved if Alb was added ($R^2 = 0.468$–0.483) to the model. The R^2 gradually improved after adding age or race variables, or both, although the degree of improvement was not large. We could not find any improvement after adding gender

Table 1—Baseline patients' characteristics (n = 11,986)

Characteristics	n or mean ± SD	%	Caucasian n or mean ± SD	%	African American n or mean ± SD	%	Hispanic n or mean ± SD	%	Asian n or mean ± SD	%	Other n or mean ± SD	%	P†
Total	11,986	100	3,963	33	4,093	34	2,521	21	402	3	1,007	8	
Age (years)	63 ± 12		65 ± 13		62 ± 12		62 ± 11		66 ± 11		63 ± 11		<0.001
Gender													
Female	6,098	51	1,824	46	2,316	57	1,252	50	211	52	495	49	<0.001
Male	5,888	49	2,139	54	1,777	43	1,269	50	191	48	512	51	
Type of diabetes													
Type 1	2,360	20	839	21	855	21	439	17	66	16	161	17	<0.001
Type 2	9,626	80	3,124	79	3,238	79	2,082	83	336	84	846	83	
Dialysis vintage (years)	2.8 ± 2.4		2.3 ± 2.0		3.2 ± 2.7		2.8 ± 2.4		2.6 ± 2.2		3.2 ± 2.7		<0.001
Laboratory findings													
Total protein (g/dL)	6.9 ± 0.5		6.6 ± 0.5		7.1 ± 0.5		6.9 ± 0.5		7.0 ± 0.5		6.9 ± 0.5		<0.001
Albumin (g/dL)	3.7 ± 0.3		3.7 ± 0.3		3.7 ± 0.3		3.7 ± 0.3		3.8 ± 0.3		3.7 ± 0.3		<0.001
Hb (g/dL)	12.0 ± 0.7		12.0 ± 0.7		12.0 ± 0.7		12.1 ± 0.7		12.0 ± 0.6		12.0 ± 0.7		<0.001
Glucose (mg/dL)	175 ± 54		179 ± 54		166 ± 53		179 ± 55		178 ± 51		175 ± 53		<0.001
HbA_{1c} (%)	6.6 ± 1.3		6.5 ± 1.2		6.5 ± 1.3		6.7 ± 1.3		6.4 ± 1.1		6.6 ± 1.3		<0.001
Dialysis information													
Dialysis time (h)	3.5 ± 0.8		3.5 ± 0.8		3.6 ± 0.8		3.5 ± 0.7		3.1 ± 0.9		3.4 ± 0.8		<0.001
Kt/V*	1.53 ± 0.33		1.52 ± 0.33		1.48 ± 0.30		1.58 ± 0.33		1.67 ± 0.38		1.60 ± 0.36		<0.001

*Kt/V was estimated by Daugirdas II equation for single pool. †P derived from ANOVA and Pearson χ^2 tests.
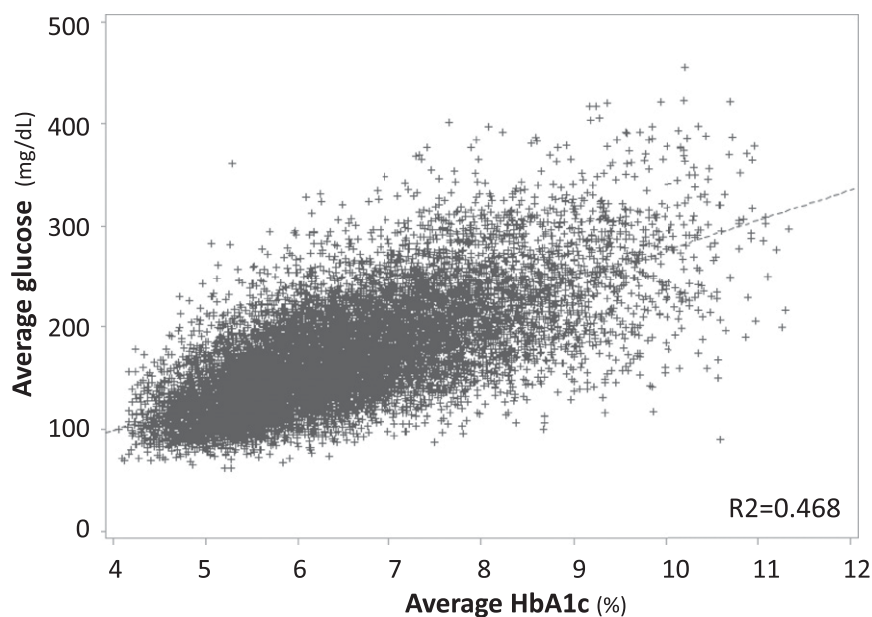
Figure 1—*Relationship between mean HbA$_{1c}$ and mean BG in each patient on HD (n = 11,986). Comparison between average HbA$_{1c}$ and AG levels in each patient (n = 11,986). The R^2 in the fitted line was 0.468.*

variable or quadratic, root, log, or exponential models. Considering the convenience for clinical use, we selected model 3 (the equation with Alb) and model 4 (the equation with Alb and Hb) as "simple" models, and the fully adjusted model (model 8) was selected as a "complex" model.

Blood glucose estimation
Next, we compared AG and estimated BG using our models and previously reported equations (ADAG and DCCT models established for nondialysis populations). Compared with previous equations (ADAG and DCCT models established for nondialysis populations; adjusted R^2 = 0.468), all our models showed better correlation (adjusted R^2 = 0.483, 0.486, and 0.491) (Fig. 2) in HD patients. In addition, the glucose levels estimated by the DCCT and ADAG models were similar to those of our models if patients had Alb level of 4.0 mg/dL and if HbA$_{1c}$ was >9.0%. However, the estimated glucose levels by the previous models were lower if patients had lower Alb levels or lower HbA$_{1c}$ levels (Table 3).

Utility of the model in race- and gender-based subgroups
Because our models suggested that race also was an independent covariate in the HbA$_{1c}$-AG equation model, we checked correlations separately in each race group. Moreover, because the number of Asians

was relatively small (*n* = 402; 3% of the study population), it was essential to check the utility of the equation in this group. As shown in Table 4, the adjusted R^2 between the AG and the estimated BG using our model 3 and model 8 in non-Hispanic whites were 0.470 and 0.479 in males and 0.466 and 0.472 in females. There was a higher correlation in African Americans (adjusted R^2 = 0.530 and 0.538 in males and 0.531 and 0.538 in females) and Hispanics (adjusted R^2 = 0.498 and 0.511 in males and 0.478 and 0.488 in females) compared with non-Hispanic whites, but a lower association among Asians (adjusted R^2 = 0.385 and 0.387 in males and 0.400 and 0.414 in females). These data suggested that this model may work especially well in African American and Hispanic populations.

CONCLUSIONS—In this large-scale cohort of 11,986 diabetic HD patients (69,764 samples), we reported new HbA$_{1c}$ and BG equation models that are at least as good or better than previous equations. To the best of our knowledge, this is the first model for HD patients showing better correlation than the previous standard formulas that were developed for nondialysis patients. Interestingly, the slope of the glucose variable in our model was almost identical to that in the ADAG model. HbA$_{1c}$ has been considered to underestimate glucose measurements in diabetic patients on HD compared with glycated albumin (4–6).

Using the ADAG and DCCT model, the estimated glucose levels tended to be lower than the AG (Table 3).

Although previous observational studies have yielded inconsistent results regarding the association between glycemic control and outcomes in diabetic HD patients, our recent study suggested that after adjusting for potential confounders, higher HbA$_{1c}$ values were associated with higher death risk in patients on maintenance HD (13,14). Therefore, HbA$_{1c}$ is considered an important clinical marker for glycemic control. There have been several other measurements that represent glycemic levels for patients with chronic kidney disease, such as glycated albumin (15) and 1,5-anhydro-D-glucitol (16). However, an ideal indicator for glycemic control in dialysis patients has not been agreed on yet. All of the proposed markers have advantages and disadvantages. For example, the accelerated destruction of erythrocytes may reduce the half-life of HbA$_{1c}$; however, glycoalbumin may be affected by an accelerated turnover of Alb with proteinuria, which is commonly observed in patients with end-stage renal disease. Nevertheless, HbA$_{1c}$ still has been one of the most widely used glycemic control indicators for diabetic patients with and without kidney disease. A clear understanding of the relationship between AG and HbA$_{1c}$ is necessary for setting appropriate BG goals for achieving specific HbA$_{1c}$ targets in dialysis patients. Our model may be useful to convert daily AG to target HbA$_{1c}$ values and vice versa. Because most HD patients are considered as having similar Hb levels, which is recommended by clinical guidelines, model 3 (AG = 59.2 + 29.4 × HbA$_{1c}$ − 20.8 × Alb) may be the most simple and practical equation for daily use.

Rambod et al. (17) reported that low HbA$_{1c}$ levels could be considered a surrogate marker of protein-energy wasting, which is a well-known predictor of mortality in dialysis patients. Similarly, we previously reported that Alb levels were associated with HbA$_{1c}$ levels (14). As shown in Table 3, the estimated glucose levels in this study were higher by ~20 mg/dL if Alb levels decreased from 4.0 to 3.0 g/dL. Patients on dialysis have a higher prevalence of hypercatabolism compared with the general population, which could affect Alb levels (18). Our results supported a simple linear relationship between mean glucose and HbA$_{1c}$ levels in a clinically relevant range of glycemia that was reported by Nathan et al.

Table 2—Relationships between the AG and the average HbA_{1c}

Model	Covariates	Mean*		Bootstrapping†	
		Adjusted R^2	RMSE	Adjusted R^2	RMSE
1	AG = −18.6 + 29.4 × HbA$_{1c}$	0.468	39.140	0.468	39.151
2	AG = 59.6 + 29.8 × HbA$_{1c}$ − 6.7 × Hb	0.475	38.871	0.475	38.879
3	AG = 59.2 + 29.4 × HbA$_{1c}$ − 20.8 × Alb	0.483	38.578	0.483	38.583
4	AG = 104.8 + 29.7 × HbA$_{1c}$ − 18.4 × Alb − 4.7 × Hb	0.486	38.453	0.486	38.457
5	AG = 25.1 + 30.4 × HbA$_{1c}$ − 19.5 × Alb + 0.4 × age	0.489	38.358	0.489	38.365
6	AG = 25.2 + 30.4 × HbA$_{1c}$ − 19.6 × Alb + 0.4 × age + 0.9 × gender	0.489	38.357	0.489	38.364
7	AG = 32.3 + 30.3 × HbA$_{1c}$ − 19.4 × Alb + 0.3 × age + race (+4.3 if A, −11.7 if AA, −3.3 if H)	0.498	37.988	0.499	37.995
8	AG = 82.9 + 30.7 × HbA$_{1c}$ − 16.5 × Alb−5.4 × Hb + 0.3 × age + race (+3.8 if A, −12.0 if AA, −3.3 if H)	0.503	37.822	0.503	37.828
9	AG = 83.1 + 30.7 × HbA$_{1c}$ − 16.6 × Alb−5.4 × Hb + 0.3 × age + 0.4 × gender + race (+3.8 if A, −11.9 if AA, −3.3 if H)	0.503	37.823	0.503	37.829
10	AG = 48.8 + 41.6 × HbA$_{1c}$ − 0.8 × (HbA$_{1c}$)^2 − 16.8 × Alb − 5.5 × Hb + 0.3 × age + race (+3.7 if A, −11.9 if AA, −3.3 if H)	0.504	37.789	0.504	37.796

A, Asian; AA, African American; H, Hispanic; RMSE, root mean square error. *Mean BG and mean HbA$_{1c}$ were used to estimate correlations. †The bootstrapping methods were used to estimate averaged BG and averaged HbA$_{1c}$.

(2), but it also revealed the importance of taking into account the Alb level in the equation between HbA$_{1c}$ and AG for dialysis patients, especially because Alb values in dialysis patients are usually lower than they are in the general population. In addition, our analysis revealed that careful interpretation of HbA$_{1c}$ is needed if patients had malnutrition and anemia, known as MIA syndrome. In these patients, equation models including Alb and Hb (model 4 or complex model) may be useful to estimate their average glucose levels.

It was reported that postprandial BG was associated with survival in HD patients (19) and there was no difference for mean amplitude of glycemic excursion between the day on and day off HD by an analysis of continuous glucose monitoring (20). In addition, as shown in the Supplementary Fig. 1, our data showed that afternoon and evening BG measurements, not fasting BG, had better correlation with their HbA$_{1c}$ levels, which was consistent with the results for patients without end-stage renal disease reported by Rohlfing et al. (1). These findings may imply that initiation of HD may be best after BG measurement. If patients start dialysis with fasting, then postprandial glucose measurement should be added. Also if subjects use maintained antidiabetes agents, BG measurement during HD should be added, because glucose levels decrease with initiation of HD when using these agents (20).

There are several limitations in this study. First, our data were not based on continuous daily BG monitoring. However, the large number of random BG samples available to us and the bootstrapping technique may minimize this problem. Furthermore, our equations obtained by bootstrapping showed similar results with the estimation obtained by using time-averaged values, suggesting robustness of our models. Second, the proportion of the
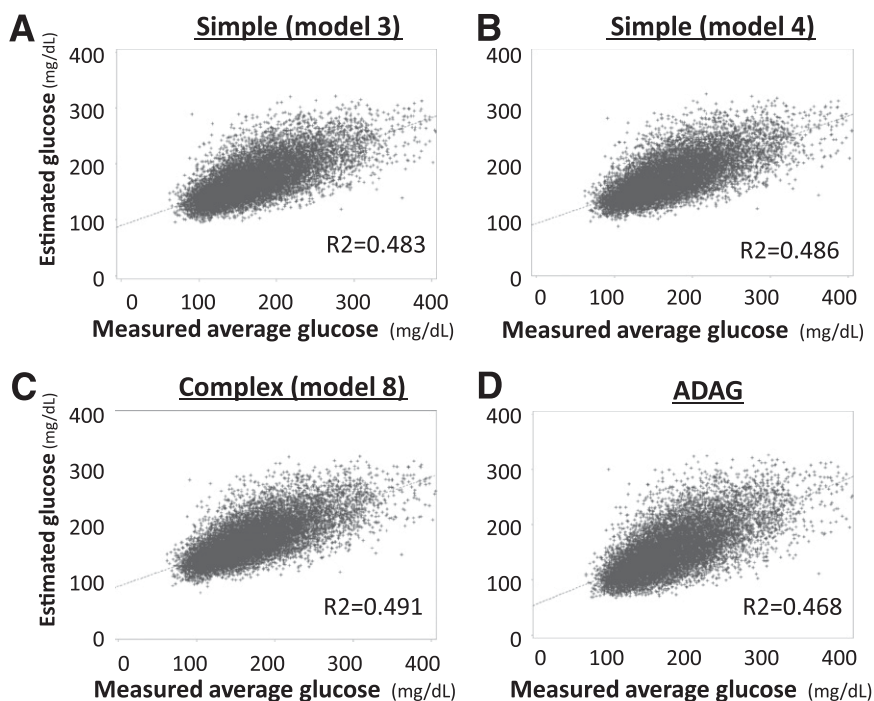

Figure 2—*Relationship between the AG and the estimated BG using estimation models. A: Relationship between AG and estimated BG using estimation models. Simple model 3: AG = 59.2 + 29.4 × HbA$_{1c}$ − 20.8 × Alb (R^2_{adj} = 0.483). B: Simple model 4 was used: AG = 104.8 + 29.7 × HbA$_{1c}$ − 18.4 × Alb − 4.7 × Hb (R^2_{adj} = 0.486). C: Complex model 8: AG = 82.9 + 30.7 × HbA$_{1c}$ −16.5 × Alb − 5.4 × Hb + 0.3 × age + race (+3.8 if Asian, −12.0 if African American, −3.3 if Hispanic) (R^2_{adj} = 0.491). D: ADAG formula: (AG = 28.7 × HbA$_{1c}$ − 46.7) (R^2_{adj} = 0.468). R^2_{adj}, adjusted R^2.*

Table 3—Estimated glucose levels at each HbA$_{1c}$ and Alb levels in the different models

HbA$_{1c}$ (%)	Alb (mg/dL)	Model 3 (+Alb)	Model 4 (+Alb,Hb)	Model 8* (complex)	DCCT model	ADAG model
		Estimated average glucose (mg/dL)				
5.0	4.0	123	133	134	101	97
5.0	3.5	133	142	143		
5.0	3.0	144	151	151		
6.0	4.0	152	162	165	136	126
6.0	3.5	163	172	173		
6.0	3.0	173	181	182		
7.0	4.0	182	192	196	172	154
7.0	3.5	192	201	204		
7.0	3.0	203	211	212		
8.0	4.0	211	222	227	208	183
8.0	3.5	222	231	235		
8.0	3.0	232	240	243		
9.0	4.0	241	252	257	243	212
9.0	3.5	251	261	265		
9.0	3.0	261	270	274		
10.0	4.0	270	281	288	279	240
10.0	3.5	280	290	296		
10.0	3.0	291	300	304		

Estimated glucose levels for whites with Hb 10.0 g/dL and age 60 years (+3.8 if Asian, −12.0 if African American, and −3.3 if Hispanic).

Asian population was small in our data set. Therefore, our model might not be representative enough for the HbA$_{1c}$-AG association in Asians. In fact, compared with other races, the correlations in Asians were relatively weak. Third, our population consisted of patients with relatively early dialysis vintage. The association between HbA$_{1c}$ and glucose may be different in patients with longer vintage, because uremia and routine use of erythropoietin could affect HbA$_{1c}$. Finally, our models may not represent patients on peritoneal dialysis (PD). Because they are exposed to a greater glucose charge present in dialysate solution, their glucose behavior may be different from that of patients on HD. In addition, lack of information on PD prescription would add more residual confounding. A large database consisting of PD patients is needed to develop HbA$_{1c}$-AG equation models for patients on PD.

In conclusion, there was a predictable relationship between HbA$_{1c}$ and AG in HD patients. Our new models for HD patients showed better correlations between HbA$_{1c}$ and AG compared with previous models. The model including Alb is better-suited for HD patients because of the lower Alb levels in this population. Similar to reporting serum creatinine with the calculated glomerular filtration rate, HbA$_{1c}$ levels should provide patients and health care providers with a more useful index of day-to-day BG levels.

Table 4—Correlations between the AG and the estimated BG in each race and gender

Race		n	Model 3 (HbA$_{1c}$+Alb)	Model 4 (HbA$_{1c}$, Alb, Hb)	Model 8 (complex)	DCCG	AGAG
			Adjusted R^2 value				
White	Female	1,824	0.466	0.470	0.472	0.454	0.454
	Male	2,139	0.470	0.473	0.479	0.452	0.452
African American	Female	2,316	0.531	0.536	0.538	0.516	0.516
	Male	1,777	0.530	0.533	0.538	0.520	0.520
Hispanic	Female	1,252	0.478	0.480	0.488	0.461	0.461
	Male	1,269	0.498	0.506	0.511	0.483	0.483
Asian	Female	211	0.400	0.401	0.414	0.362	0.362
	Male	191	0.385	0.379	0.387	0.369	0.369
Others	Female	495	0.464	0.469	0.481	0.456	0.456
	Male	512	0.426	0.433	0.441	0.416	0.416
Total		11,986	0.483	0.486	0.491	0.468	0.468

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