# No Ethnic Differences in the Association of Glycated Hemoglobin With Retinopathy

## The National Health and Nutrition Examination Survey 2005–2008

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**OBJECTIVE**—Current recommendations for the use of hemoglobin $A_{1c}$ ($HbA_{1c}$) in diabetes screening and diagnosis aim to identify those at greatest risk for diabetic microvascular complications. However, there is current controversy regarding the clinical implications of ethnic differences in $HbA_{1c}$ values. The objective of this study was to determine whether the association between $HbA_{1c}$ and retinopathy differs by ethnic group in a representative sample of U.S. adults.

**RESEARCH DESIGN AND METHODS**—The study was a cross-sectional analysis of 2,945 non-Hispanic white, 1,046 non-Hispanic black, and 1,231 Hispanic American participants aged ≥40 years from the 2005–2008 National Health and Nutrition Examination Survey.

**RESULTS**—Among nondiabetic adults, the mean $HbA_{1c}$ was 5.5% in non-Hispanic whites, 5.7% in non-Hispanic blacks, and 5.6% in Hispanic Americans. Among those with diagnosed diabetes, mean $HbA_{1c}$ was 6.9% in non-Hispanic whites, 7.5% in non-Hispanic Blacks, and 7.7% in Hispanic Americans. Overall, non-Hispanic blacks had the highest prevalence of retinopathy. In multivariable logistic models, $HbA_{1c}$ clinical categories were strongly associated with prevalent retinopathy. However, the magnitude of the association did not differ by ethnic group (all *P* values for interaction ≥ 0.7). Similar results were observed with $HbA_{1c}$ modeled continuously (per one percentage point) and stratified by diabetes status (all *P* for interactions > 0.3).

**CONCLUSIONS**—We observed no ethnic differences in the association of $HbA_{1c}$ with retinopathy. These data do not support ethnic-specific cut points for $HbA_{1c}$ for diagnosis or screening of diabetes mellitus.

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Hemoglobin $A_{1c}$ ($HbA_{1c}$) was recently recommended for use in the diagnosis of diabetes (1,2). Recommended clinical categories for diabetes diagnosis using $HbA_{1c}$ largely are based on the established association of $HbA_{1c}$ with prevalent retinopathy (3–6) and evidence from clinical trials demonstrating that lowering $HbA_{1c}$ can reduce microvascular complications (7). Nonetheless, recent studies document persistent ethnic differences in $HbA_{1c}$ values (8–12), raising concerns that the performance of $HbA_{1c}$ may differ in certain subpopulations and that new recommendations for the use of $HbA_{1c}$ for diagnosis might be problematic in individuals of non-European ancestry (13–19). Data about the association of $HbA_{1c}$ with clinical outcomes in different ethnic groups are critical to inform this debate.

The objective of this study was to characterize the ethnic-specific associations between $HbA_{1c}$ and retinopathy in the U.S. population aged 40 years and older using data from the 2005–2008 National Health and Nutrition Examination Survey (NHANES) and to formally test for effect modification by ethnicity.

## RESEARCH DESIGN AND METHODS

### Study population

The NHANES is a cross-sectional, nationally representative survey of the U.S. civilian noninstitutionalized population conducted by the National Center of Health Statistics, Centers for Disease Control and Prevention (20). In this study, we included 2,945 non-Hispanic white, 1,046 non-Hispanic black, and 1,231 Hispanic American participants aged 40 years or older who had complete information on the variables of interest in the 2005–2008 NHANES. A review board for human subjects approved data collection procedures, and written informed consent was obtained from all study participants.

### Measurements

$HbA_{1c}$ measurements were obtained using high-performance liquid chromatography standardized to the Diabetes Control and Complication Trial assay (20). Demographic information (including ethnicity, sex, education, and income), smoking history, and health history were determined by self-report. Height, weight, blood pressure, and lipids were measured using standard procedures (21,22). A history of diabetes was defined as self-reported diagnosis of diabetes (not during pregnancy for women) or current insulin use.

Retinal imaging was performed on individuals who were aged ≥40 years using a Canon Non-Mydriatic Retinal Camera CR6–45NM; participants with blindness, eye infections, or eye patches were excluded. Detailed information about methodology is available elsewhere (21,22). Briefly, two 45-degree nonmydriatic digital images of the retina

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were obtained from each eye, and graders at the University of Wisconsin Ocular Epidemiology Reading Center evaluated the images. Retinopathy level was determined as described by the Early Treatment Diabetic Retinopathy Study (EDTRS) and ranged from 10–80 (23). We defined "any retinopathy" as an EDTRS level of 14 or higher in the worse eye, thereby classifying individuals as having either no retinopathy or mild nonproliferative retinopathy or worse (21,22).

### Statistical analysis

We used logistic regression models to evaluate the independent association between $HbA_{1c}$ (modeled in clinical categories and continuously) and prevalent retinopathy. We formally tested for interaction by ethnic group. Analyses were stratified by diabetes status, and prevalence estimates were age-standardized to the 2010 U.S. Census to obtain estimates of the proportion of individuals with retinopathy by $HbA_{1c}$ category and diabetes status.

Adjustment variables included age, sex, BMI, hypertension status, history of coronary heart disease, total cholesterol, educational attainment, income level, and smoking status. In analyses modeling $HbA_{1c}$ as a categorical variable, the sample was stratified using clinical categories of $HbA_{1c}$ (in those without diagnosed diabetes: <5.7%, 5.7–6.4%, and ≥6.5%; in those with diagnosed diabetes: <7% and ≥7%). The nondiabetic group with $HbA_{1c}$ values in the normal range (<5.7%) served as the reference group. Sensitivity analyses were conducted modeling $HbA_{1c}$ using deciles (tenths) (4,5) and using different EDTRS cut points to define retinopathy (23). *P* values for interactions were derived from Wald tests. All analyses incorporated the NHANES sample weights and accounted for the complex sample survey design using standard methods (20).

**RESULTS**—Overall, the mean age was 57 years, the population was 48% male, and the mean $HbA_{1c}$ was 5.7%. Details regarding population characteristics stratified by diabetes status and ethnicity are summarized in Table 1. Among nondiabetic adults, the mean $HbA_{1c}$ was 5.5% in non-Hispanic whites, 5.7% in non-Hispanic blacks ($P < 0.001$ compared with non-Hispanic whites), and 5.6% in Hispanic Americans ($P = 0.002$ compared with non-Hispanic whites). Among those with diagnosed diabetes, mean $HbA_{1c}$ was 6.9% in non-Hispanic whites, 7.5% in non-Hispanic Blacks ($P = 0.002$ compared with non-Hispanic whites), and 7.7% in Hispanic Americans ($P < 0.001$ compared with non-Hispanic whites). In the subgroup of individuals with diagnosed diabetes, the mean duration of diabetes was 10 years in non-Hispanic whites, 11 years in non-Hispanic blacks, and 9 years in Hispanics; there was no significant difference in mean duration of diabetes by ethnicity ($P > 0.05$ for each group compared with non-Hispanic whites).

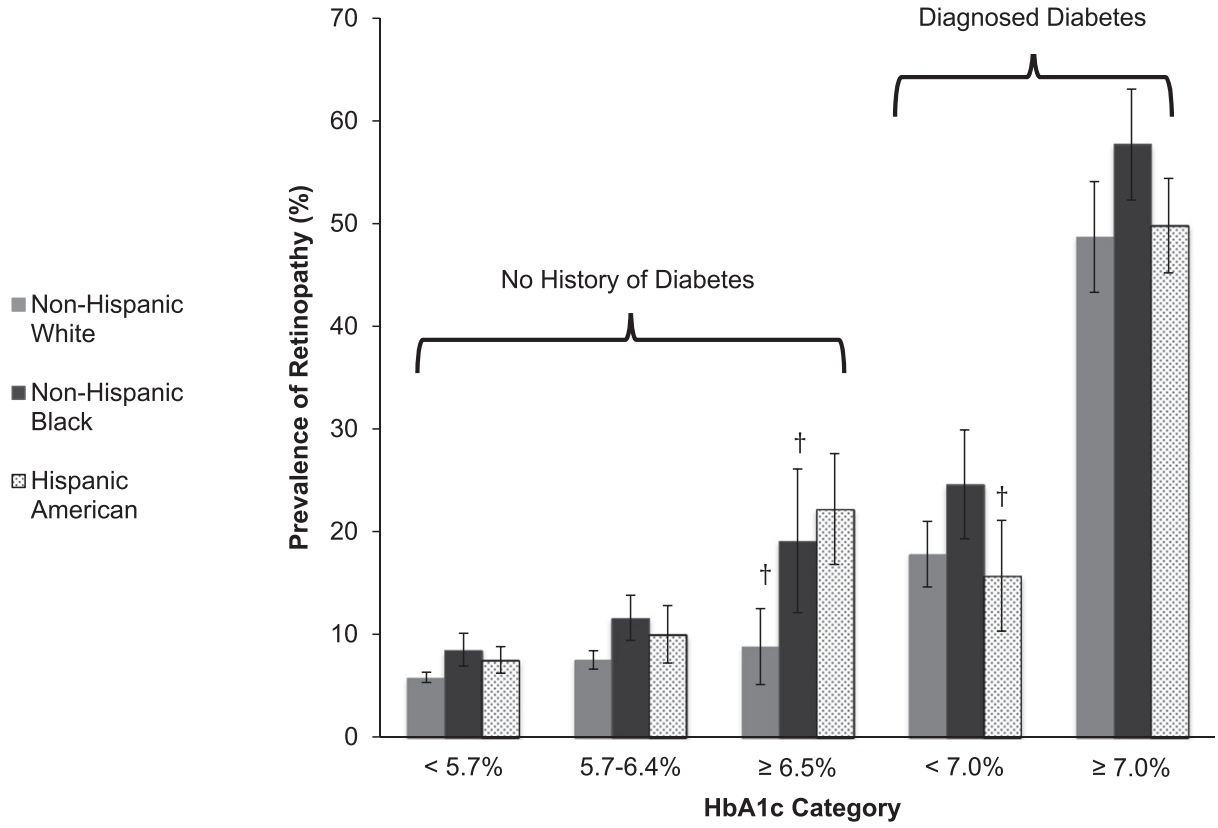
The prevalence estimates for retinopathy by ethnic group and diabetes status are shown in Fig. 1. Among those in the lowest $HbA_{1c}$ category (<5.7%) who were aged ≥40 years with no history of diabetes, the prevalence of retinopathy was 6% (95% CI, 5–7) in non-Hispanic whites, 9% (5–12) in non-Hispanic blacks, and 8% (5–10) in Hispanic Americans. The prevalence of retinopathy in persons with undiagnosed diabetes ($HbA_{1c}$ ≥6.5%) was 9% (1–17) in non-Hispanic whites, 19% (5–34) in non-Hispanic blacks, and 22% (11–33) in Hispanic Americans. In persons with diagnosed diabetes, the prevalence of retinopathy in those with $HbA_{1c}$ <7% was 18% (95% CI, 11–24) in non-Hispanic whites, 25% (95% CI, 14–35) in non-Hispanic blacks, and 16% (95% CI, 4–27) in Hispanic Americans. Finally, the prevalence of retinopathy in those with diagnosed diabetes and $HbA_{1c}$ ≥7% was 49% (37–60) in non-Hispanic whites, 57% (46–69) in non-Hispanic blacks, and 50% (40–59) in Hispanic Americans. The proportion of individuals with more severe retinopathy was higher among non-Hispanic black and Hispanic participants compared with non-Hispanic whites; the proportions of retinopathy severity scores by group are shown in Supplementary Fig. 1.

In crude and adjusted logistic models (Table 2), $HbA_{1c}$ categories were strongly associated with prevalent retinopathy. The magnitude of the association did not differ by ethnic group (all *P* for interactions ≥ 0.7). Similar results were observed in analyses with $HbA_{1c}$ modeled continuously (per one percentage point) and stratified by diabetes status (Table 3 and Supplementary Fig. 2). Additional adjustment for diabetes duration or insulin use in the subgroup of participants with diagnosed diabetes did not materially alter our results. Our results were similar in a sensitivity analysis examining the association of $HbA_{1c}$ categorized into

**Table 1**—*Selected characteristics of U.S. adults aged ≥40 years, stratified by diagnosed diabetes status and ethnicity, NHANES 2005–2008*

| | No history of diabetes (*n* = 4,413) | | | Diagnosed diabetes (*n* = 809) | | |
|---|---|---|---|---|---|---|
| Characteristics | Non-Hispanic white | Non-Hispanic black | Hispanic American | Non-Hispanic white | Non-Hispanic black | Hispanic American |
| Unweighted *n* | 2,612 | 805 | 996 | 333 | 241 | 235 |
| Age (years) | 56.7 ± 0.5 | 53.5 ± 0.4 | 51.9 ± 0.4 | 62.8 ± 0.6 | 59.0 ± 0.9 | 57.8 ± 1.0 |
| Male (%) | 47.8 ± 0.9 | 45.3 ± 1.7 | 49.2 ± 1.7 | 50.1 ± 3.9 | 44.2 ± 4.1 | 44.6 ± 4.7 |
| Education ≥high school (%) | 87.7 ± 1.5 | 73.5 ± 2.4 | 54.7 ± 2.5 | 78.1 ± 2.5 | 65.9 ± 3.2 | 44.1 ± 6.5 |
| Income above poverty level (%) | 94.4 ± 0.8 | 85.3 ± 1.7 | 77.8 ± 2.6 | 91.0 ± 1.3 | 79.1 ± 2.6 | 77.1 ± 3.6 |
| BMI ($kg/m^2$) | 28.5 ± 0.2 | 30.0 ± 0.3 | 29.3 ± 0.3 | 32.9 ± 0.3 | 33.9 ± 0.7 | 30.8 ± 0.6 |
| Waist circumference (cm) | 99.5 ± 0.4 | 99.4 ± 0.5 | 98.6 ± 0.6 | 112.2 ± 0.6 | 109.0 ± 1.6 | 103.6 ± 1.2 |
| Current smoker (%) | 20.2 ± 1.6 | 27.8 ± 2.0 | 18.7 ± 1.2 | 14.5 ± 2.2 | 23.2 ± 3.0 | 13.0 ± 2.0 |
| Diagnosed hypertension (%) | 38.3 ± 1.3 | 46.6 ± 1.8 | 26.5 ± 1.7 | 70.5 ± 3.1 | 77.3 ± 3.5 | 54.2 ± 6.1 |
| $HbA_{1c}$ (%) | 5.5 ± 0.02 | 5.7 ± 0.03 | 5.6 ± 0.03 | 6.9 ± 0.09 | 7.5 ± 0.1 | 7.7 ± 0.2 |
| Any retinopathy (%) | 6.2 ± 0.4 | 9.2 ± 1.3 | 9.0 ± 1.3 | 32.4 ± 2.5 | 42.6 ± 4.5 | 34.5 ± 3.6 |

Data are weighted means ± SE or proportions ± SE.




| | < 5.7% | 5.7–6.4% | ≥ 6.5% | < 7.0% | ≥ 7.0% |
|---|---|---|---|---|---|
| Non-Hispanic White | 5.8 ± 0.5 | 7.5 ± 0.9 | 8.8 ± 3.7† | 17.8 ± 3.2 | 48.7 ± 5.4 |
| Non-Hispanic Black | 8.5 ± 1.6 | 11.6 ± 2.2 | 19.1 ± 7.0† | 24.6 ± 5.3 | 57.7 ± 5.4 |
| Hispanic American | 7.5 ± 1.3 | 10.0 ± 2.8 | 22.2 ± 5.4 | 15.7 ± 5.4† | 49.8 ± 4.6 |

**Figure 1**—*Age-adjusted prevalence of any retinopathy by ethnic group and $HbA_{1c}$ category among U.S. adults aged ≥40 years, 2005–2008. Retinopathy was defined as an ETDRS level of 14 or greater (21,22). Estimates are weighted proportions ± SE and are age-standardized to the 2010 U.S. Census population. †Estimate may be unreliable because the SE is greater than 30% of the estimate.*

tenths (Supplementary Fig. 3). Our results were also robust to different definitions of retinopathy (Supplementary Tables 1 and 2). Finally, results from linear regression models (log-transforming retinopathy score) and ordinal logistic regression models predicting retinopathy severity were also similar (results not shown).

**CONCLUSIONS**—We found no ethnic differences in the association of $HbA_{1c}$ with prevalent retinopathy in this nationally representative sample of U.S. adults aged 40 years and older. Consistent with previous studies (9,24–27), the prevalence of retinopathy was substantially higher in non-Hispanic blacks and Hispanics compared with non-Hispanic whites. This may partially reflect ethnic disparities in the diagnosis of diabetes and management of hyperglycemia among individuals with diabetes. Consistent with previous analyses of NHANES data (12,28,29), we observed higher $HbA_{1c}$ values in non-Hispanic blacks and Hispanics compared with non-Hispanic whites. However, we found no evidence that ethnic group modified the relative association of $HbA_{1c}$ with prevalent retinopathy. These findings are consistent with other studies that have demonstrated similar patterns of association between $HbA_{1c}$ with microvascular conditions (6) and long-term vascular outcomes in non-Hispanic white and black populations (30). Our results were robust to different categorizations of $HbA_{1c}$ and definitions of retinopathy.

Current clinical diagnostic categories for $HbA_{1c}$ largely are based on cross-sectional analyses of the association of $HbA_{1c}$ with retinopathy (1,3,31), where the primary goal was to identify points along the continuum of $HbA_{1c}$ where the likelihood of microvascular abnormalities increase (4,6,26). Taken together, our results support the current guidelines for the use of $HbA_{1c}$ for the diagnosis of diabetes and suggest that current clinical cut points should be interpreted similarly in whites, blacks, and Hispanics. These results should help alleviate concerns regarding the use of $HbA_{1c}$ for diagnosis and monitoring of diabetes in diverse populations.

Important strengths of this study include the rigorous and standardized measurement of $HbA_{1c}$, retinopathy, and

**Table 2—*Unadjusted and adjusted odds ratios for retinopathy by ethnicity, diagnosed diabetes status, and $HbA_{1c}$ category among adults aged ≥40 years, NHANES 2005–2008***

| | No history of diabetes | | | Diagnosed diabetes | |
|---|---|---|---|---|---|
| | <5.7% | 5.7–6.4% | ≥6.5% | <7.0% | ≥7.0% |
| Crude (*P* for interaction = 0.71) | | | | | |
| Non-Hispanic white | 1.00 (ref) | 1.49 (1.01–2.19)* | 1.48 (0.59–3.72) | 4.46 (3.25–6.14)* | 16.21 (10.61–24.75)* |
| Non-Hispanic black | 1.00 (ref) | 1.60 (0.84–3.07) | 3.16 (1.26–7.92)* | 4.37 (2.19–8.76)* | 18.47 (8.94–38.14)* |
| Hispanic American | 1.00 (ref) | 1.26 (0.64–2.46) | 3.38 (1.62–7.05)* | 2.27 (0.93–5.54) | 11.60 (6.75–19.93)* |
| Adjusted for age and sex (*P* for interaction = 0.72) | | | | | |
| Non-Hispanic white | 1.00 (ref) | 1.30 (0.89–1.90) | 1.22 (0.47–3.16) | 3.77 (2.66–5.36)* | 13.91 (8.96–21.60)* |
| Non-Hispanic black | 1.00 (ref) | 1.45 (0.78–2.73) | 2.71 (1.06–6.93)* | 3.51 (1.82–6.78)* | 16.48 (8.17–32.28)* |
| Hispanic American | 1.00 (ref) | 1.23 (0.64–2.36) | 3.32 (1.61–6.86)* | 2.21 (0.87–5.64) | 12.07 (6.63–21.97)* |
| Multivariable† adjusted models (*P* for interaction = 0.70) | | | | | |
| Non-Hispanic white | 1.00 (ref) | 1.23 (0.84–1.80) | 1.16 (0.40–3.32) | 3.68 (2.40–5.62)* | 14.10 (8.98–22.14)* |
| Non-Hispanic black | 1.00 (ref) | 1.45 (0.77–2.74) | 2.88 (1.13–7.43)* | 3.22 (1.64–6.34)* | 15.79 (7.45–33.43)* |
| Hispanic American | 1.00 (ref) | 1.34 (0.68–2.62) | 3.58 (1.70–7.53)* | 2.35 (0.94–5.86) | 11.96 (6.18–23.17)* |

*$P < 0.05$ compared with the reference (ref) group. †Adjusted for age, sex, BMI (kg/m$^2$), hypertension status (yes/no based on self-report or measured blood pressure), history of coronary heart disease (yes/no), total cholesterol (mg/dL), education (<12 years or ≥12 years), income (poverty income ratio <1 or ≥1), and smoking status (current, former, or never).

covariates in NHANES. Our analyses included large numbers of non-Hispanic blacks and Hispanic Americans using nationally representative data from the U.S. civilian, noninstitutionalized population. Nonetheless, because retinopathy is relatively uncommon in the general population, our estimates for certain population subgroups (for example, non-Hispanics without diabetes and with $HbA_{1c}$ ≥6.5% and Hispanics with diagnosed diabetes and $HbA_{1c}$ <7%) are imprecise. Furthermore, because of the cross-sectional nature of this study, we are unable to establish the temporality of the observed associations.

The data presented do not support the contention that $HbA_{1c}$ is artifactually elevated in non-Hispanic black populations, as has been claimed by some experts. Indeed, the higher prevalence of retinopathy in non-Hispanic blacks without diagnosed diabetes and across $HbA_{1c}$ categories highlights a need for more aggressive screening and prevention efforts to mitigate microvascular complications in this group. Overall, our results support current recommendations for the use of $HbA_{1c}$ for diagnosis of diabetes, not only in non-Hispanic white populations, but also for non-Hispanic black and Hispanic individuals.

**Table 3—*Odds ratios per one percentage point $HbA_{1c}$ for retinopathy by ethnicity and diabetes status among adults aged ≥40 years, NHANES 2005–2008***

| | No history of diabetes | Diagnosed diabetes |
|---|---|---|
| Crude | | |
| Non-Hispanic white | 1.47 (1.15–1.89) | 1.60 (1.32–1.94) |
| Non-Hispanic black | 1.34 (1.01–1.77) | 1.34 (1.15–1.58) |
| Hispanic American | 1.43 (1.16–1.76) | 1.56 (1.24–1.96) |
| *P* for interaction | 0.89 | 0.31 |
| Adjusted for age and sex | | |
| Non-Hispanic white | 1.37 (1.05–1.79) | 1.65 (1.36–1.98) |
| Non-Hispanic black | 1.33 (1.00–1.78) | 1.39 (1.15–1.68) |
| Hispanic American | 1.38 (1.11–1.72) | 1.68 (1.27–2.20) |
| *P* for interaction | 0.99 | 0.33 |
| Multivariable* adjusted models | | |
| Non-Hispanic white | 1.33 (0.98–1.80) | 1.73 (1.43–2.10) |
| Non-Hispanic black | 1.34 (1.01–1.77) | 1.43 (1.15–1.77) |
| Hispanic American | 1.41 (1.12–1.78) | 1.71 (1.31–2.24) |
| *P* for interaction | 0.94 | 0.38 |

*Adjusted for age, sex, BMI (kg/m$^2$), hypertension status (yes/no based on self-reported or measured blood pressure), history of coronary heart disease (yes/no), total cholesterol (mg/dL), education (<12 years or ≥12 years), income (poverty income ratio <1 or ≥1), and smoking status (current, former, or never).

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J.K.B. conducted the analyses and wrote the draft of the manuscript. F.L.B. and E.S. provided input on the interpretation of data and reviewed and edited the manuscript. E.S. was involved in the planning of methods and supervision of data analysis. J.K.B. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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