

COMMUNITY SCREENING FOR PRE-DIABETES AND DIABETES USING HbA1c LEVELS IN HIGH-RISK AFRICAN AMERICANS AND LATINOS

Objective: To evaluate community screening using HbA1c levels in high risk African Americans and Latinos in those not known to have diabetes.

Design: HbA1c levels were measured in 1542 African Americans and Latinos aged ≥ 40 years with one or more of the following risk factors: family history in first degree relatives, waist circumference ≥ 40 inches in males or ≥ 35 inches in females, and hypertension, either treatment for or a measured BP of $\geq 140/90$ mm Hg. Oral glucose tolerance tests (OGTT) were offered to those meeting the HbA1c criterion for pre-diabetes.

Setting: Churches, community health fairs, senior citizen sites.

Participants: People without known diabetes.

Main Outcome Measures: Proportion of people meeting the HbA1c criteria for pre-diabetes (5.8–6.4%) and diabetes ($\geq 6.5\%$).

Results: 32% had one, 50% had two and 18% had three risk factors. By HbA1c criteria, 40% had pre-diabetes and 25% had diabetes. Increased waist circumference was the most common risk factor followed by a positive family history, and lastly, hypertension. Each individual risk factor was significantly ($P < .001$) and progressively more common as glycemia increased. Each additional risk factor increased the odds of pre-diabetes or diabetes by 2- to 4-fold. In individuals with pre-diabetes who underwent an OGTT, 59% were normal, 35% had pre-diabetes and only 6% had diabetes.

Conclusions: Community screening of high risk African Americans and Latinos with HbA1c levels identifies a large proportion of people with pre-diabetes and diabetes. Those identified with pre-diabetes are unlikely to meet the OGTT criteria for diabetes. (*Ethn Dis.* 2014;24[2]:195–199)

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INTRODUCTION

Diabetes is more common in African Americans and Latinos than in the general population¹ and their medical outcomes are worse.² Tight diabetes control early in the course of diabetes has a beneficial effect many years later yet control has deteriorated in both type 1^{3–8} and type 2⁹ diabetes. Therefore, it is very important to identify minority individuals early in the course of their disease progression and direct them to appropriate preventive measures for those with pre-diabetes or to treatment for those with diabetes. It is well-established that African Americans and Latinos are more likely to be uninsured and have less access to medical care;¹⁰ in some cases, community screenings are one of the only opportunities to detect diabetes in these populations. The American Diabetes Association (ADA), however, does not recommend community screening for diabetes because of poor follow-up of those who test positive with fingerstick

glucoses and the testing of many people at low risk.¹¹ This article will describe our experience with screening high-risk African American and Latino individuals for pre-diabetes and diabetes with HbA1c levels in community settings, which has the potential of meeting the ADA objections.

METHODS

The purpose of the community screening reported in this article was to identify potential participants for a study of vitamin D supplementation in a minority population; a subset of those with both pre-diabetes and hypovitaminosis D were subsequently selected for our study.¹² Participants were evaluated at 37 churches, 10 health fairs, 7 community events, 2 clinics and a few responded to flyers. The IRB at Charles R. Drew University approved this study. Because screening for diabetes often takes place at community health fairs, churches, senior citizen sites, etc without an informed consent being obtained, the IRB did not require it for the screening HbA1c test. However, for those with pre-diabetes defined by screening HbA1c levels 5.8%–6.4% who agreed to undergo an oral glucose tolerance test (OGTT), an informed consent for that test was required. For those who qualified and entered the study, another informed consent that described the randomized study itself was obtained.

We used the lower HbA1c value of 5.8% because the vitamin D study began before the ADA recommended the range of 5.7%–6.4% to diagnose pre-diabetes.¹¹ Also the 5.8% value yielded the highest combination of sensitivity (86%) and specificity (92%) for diabetes in an NHANES popula-

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tion.¹³ The OGTT criteria for pre-diabetes used in the our study were a fasting plasma glucose (FPG) concentration of 110–125 mg/dL and/or a 2-hour glucose value of 140–199 mg/dL. The World Health Organization lower limit of 110 mg/dL¹⁴ to define pre-diabetes was used instead of the ADA lower limit of 100 mg/dL¹¹ because in the vitamin D study, reversion to normal, <110 mg/dL as defined by the WHO criterion, would be easier to demonstrate than using the ADA criterion. The glucose criteria for the diagnosis of diabetes were a FPG ≥ 126 mg/dL and/ or a 2-hour value on the OGTT of ≥ 200 mg/dL.¹¹ The HbA1c criterion for the diagnosis of diabetes was $\geq 6.5\%$.¹¹

We screened 1542 African American and Latino participants, without a history of diabetes, ≥ 40 years old with one or more of the following 3 risk factors for diabetes: 1) family history in first degree relatives; 2) waist circumference (measured at the umbilicus) of ≥ 40 inches in males or ≥ 35 inches in females; and 3) hypertension, either being treated or newly discovered at the screening [BP $\geq 140/90$ mm Hg]). We used HbA1c Now+, manufactured by Bayer HealthCare, LLC, Diabetes Care. A direct comparison of 178 HbA1c levels in 110 individuals with and without diabetes by a TOSOH ion exchange HPLC method (ie, a Diabetes Control and Complications Trial aligned assay) and the Bayer HbA1c Now+ method correlated very well ($r=.96$) and revealed the following relationship: Bayer = 1.01 TOSOH + 0.14.¹⁵ Therefore, the HbA1c Bayer values were on average only .1% less than a standard laboratory method.

The 3 groups (normal, pre-diabetes, diabetes) were compared using the chi-square test for homogeneity. A more involved analysis considered a multivariate logistic model with the dependent variable being normal/pre-diabetes/diabetes and the independent variables consisting of the number of risk factors,

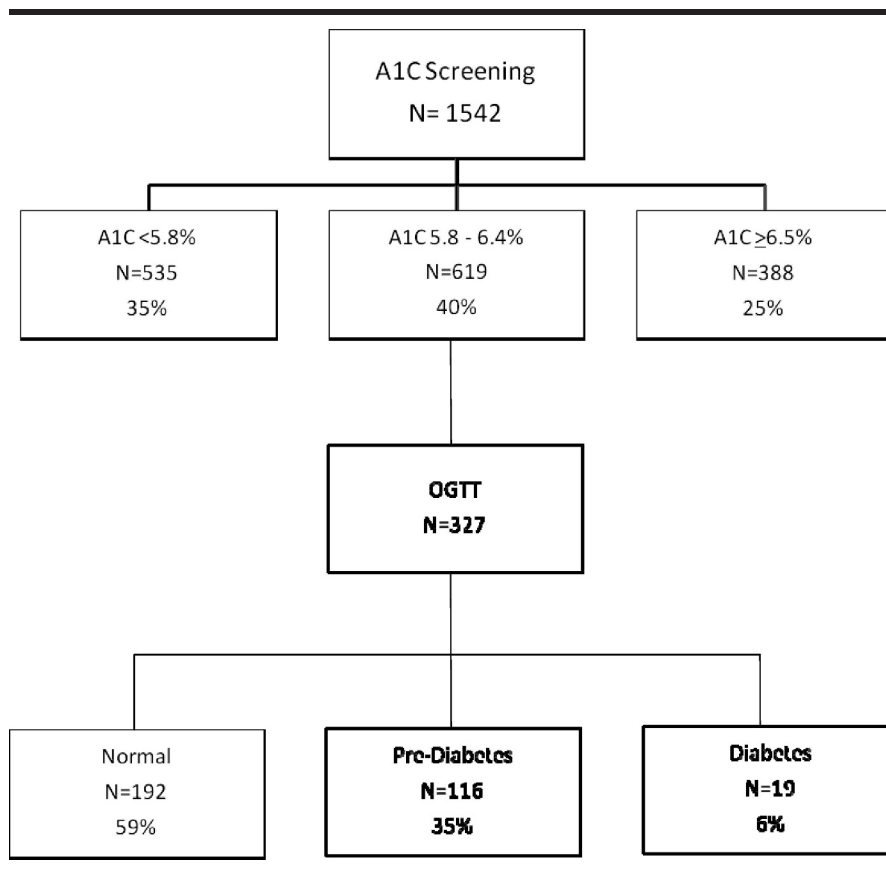


Fig 1. Flow diagram of screening and subsequent oral glucose tolerance tests (OGTT)

age, race/ethnicity and sex. Since the dependent variable was defined as a trichotomy, a polytomous logistic model was used.¹⁶

RESULTS

The 1542 African Americans and Latinos with one or more risk factors for diabetes screened ranged in age from 40–93 years and had HbA1c levels ranging from 4.3% to 13.0%. There were 422 African Americans (126 men and 296 women) and 1120 Latinos (400 men and 711 women). The proportion that had pre-diabetes or diabetes based on HbA1c criteria is shown in Figure 1 and Table 1 and is similar between African Americans and Latinos and sexes. Thirty-two percent had one, 50% had two and 18% had all three risk factors. The distribution of

risk factors in those who were normal, had pre-diabetes or diabetes is shown in Table 2. Each of the risk factors as well as the number of risk factors was significantly different among the three groups; each risk factor was significantly more likely to be present as glycemia worsened. Normal individuals were significantly more likely to have only one risk factor while those with diabetes were significantly more likely to have three risk factors. The sensitivity and specificity of each risk factor for the diagnosis of pre-diabetes and diabetes by the HbA1c criteria, shown in Table 3, were similar for pre-diabetes and diabetes. Sensitivities were highest for weight circumference followed by family history and hypertension.

For every year older than 40, the risk of having pre-diabetes or diabetes increased by 2% ($P<.001$) (data not shown). Compared to normal individu-

Table 1. African American and Latino individuals with one or more risk factors for diabetes, %

Population	Low Risk (HbA1c <5.8%)	High Risk (Pre-diabetes) (HbA1c 5.8–6.4%)	Diabetes (HbA1c ≥6.5%)
Entire, N=1542	35%	40%	25%
Males, n=535	36%	36%	28%
Females, n=1007	34%	42%	24%
African Americans, n=422	33%	40%	27%
Males, n=126	32%	39%	29%
Females, n=296	34%	40%	26%
Latino, n=1120	35%	40%	25%
Males, n=409	37%	36%	27%
Females, n=711	34%	43%	23%

als, each additional risk factor significantly increased the odds of pre-diabetes by 1.9 (95% CI; 1.6–2.3) and of diabetes by 3.8 (3.1–4.8) (both $P < .001$). Compared to individuals with pre-diabetes, each additional risk factor increased the odds of diabetes by 2.1 (1.7–2.6) ($P < .001$).

Slightly over half of individuals, with pre-diabetes by the HbA1c criterion, who were offered an OGTT, completed the procedure. Of the ones who underwent the OGTT, thirty-five percent were normal, 59% had pre-diabetes by the glucose criteria and only 6% met the criteria for diabetes.

DISCUSSION

There are 26 million people with diabetes in the United States¹⁷ and approximately 25% are unaware that they have it.¹¹ Since almost every one with type 2 diabetes is asymptomatic,¹¹ the

ADA suggests opportunistic screening for diabetes in individuals ≥ 45 years every 3 years.¹¹ There are over 50 million people in the United States without medical insurance and even if the Affordable Care Act is fully implemented, 31 million will remain without insurance. These people visit emergency rooms and urgent care centers when an acute medical situation arises. Furthermore, many people are underinsured (high co-pays and deductibles) and do not visit physicians on a routine basis. Finally, many policies under the Affordable Care Act will lead to underinsurance. Minorities constitute a high proportion of the uninsured and underinsured population.¹⁰ A likely way in which these individuals will be diagnosed with diabetes is through community screenings or when they visit emergency rooms and urgent care centers for other acute medical problems.

In our study, two-thirds of African Americans and Latinos ≥ 40 years of age with ≥ 1 of 3 easily recognized risk factors

The risk of pre-diabetes and diabetes progressively increased with more individual risk factors.

(central obesity, hypertension, positive family history in a first degree relative) had pre-diabetes (40%) or diabetes (25%) by HbA1c criteria. The most common risk factor was central obesity and it was the most sensitive in those who met the HbA1c criteria for pre-diabetes or diabetes. The risk of pre-diabetes and diabetes progressively increased with more individual risk factors. However, to facilitate the screening process, one could use only the factor of central obesity since it is easily evaluated.

It was striking that in the 327 African Americans and Latinos with pre-diabetes by the HbA1c criterion who underwent an OGTT, only 6% met the glucose criteria for diabetes. This is in marked contrast to the Caucasian population in which glucose criteria for dysglycemia in people not known to have diabetes are more sensitive than the HbA1c criteria.^{18–30} This difference is no doubt due to the fact that both Latinos^{23,31} and African Americans^{23,32–35} have higher HbA1c levels for a given glucose concentration compared with Caucasians.

The ADA does not recommend community screening for diabetes.¹¹ One of the reasons given is that too many low risk individuals will be tested. Testing only those African Americans and Latinos with one or more the risk factors listed here certainly meets that objection. The second ADA objection is that follow-up of positive tests is poor. Screening typically involves measuring glucose levels with glucose meters which are most always random. Random glucose values depend on the amount of carbohydrate eaten at the previous meal and the duration of time between ingestion of the meal and the test. The

Table 2. Distribution of risk factors

	HbA1c Level			P
	<5.8%, n=535	5.8–6.4%, n=619	≥6.5%, n=388	
Waist circumference ^a	70%	79%	84%	<.001
Family history	56%	68%	73%	<.001
Hypertension ^b	34%	42%	61%	<.001
1 risk factor	50%	27%	15%	<.001
2 risk factors	41%	57%	51%	.003
3 risk factors	9%	16%	34%	<.001

^aMales ≥ 40 inches, females ≥ 35 inches.

^bUnder treatment or newly discovered (BP $\geq 140/90$ mm Hg) at screening.

Table 3. Relationship between risk factors and HbA1c criteria for the diagnosis of pre-diabetes and diabetes

Risk Factors	n	Pre-diabetes		Diabetes	
		Sensitivity	Specificity	Sensitivity	Specificity
Waist circumference ^a	1192	79.2%	23.9%	84.3%	25.0%
Hypertension ^b	676	41.7%	54.7%	60.1%	61.7%
Family history	1001	68.0%	37.2%	72.9%	37.8%

^aMales ≥40 inches, females ≥35 inches.

^bUnder treatment or newly discovered (BP ≥140/90 mm Hg) at screening.

ADA does not have criteria for a positive random glucose test in asymptomatic individuals. It is likely that many people with a positive screening test, on more formal testing will not have diabetes, or possibly, not even pre-diabetes. Therefore, there is less impetus for people with positive glucose tests to follow up than there would be with a HbA1c value ≥6.5% which actually diagnoses diabetes, if confirmed.

Fingerstick HbA1c tests are more expensive than glucose tests. However, many community screenings are underwritten by organizations that may be able to obtain point-of-care HbA1c assays as a donation or at least bargain effectively for a reduced bulk purchase price. If only high risk individuals in African American and Latino communities are tested, there will be fewer tests carried out than in the usual community screenings. Since so few African Americans and Latinos with pre-diabetes by the HbA1c criterion had diabetes by the glucose criteria, there is little need for them to have further testing for diabetes. Those with diabetes by the HbA1c criterion will hopefully be more motivated to seek further medical intervention.

There are several limitations to this study. Point-of-care HbA1c assays are not recommended for diagnosing diabetes.³⁶ Although the assay used in this study correlated well with laboratory assays, the screening values are not used to diagnose diabetes but simply to identify individuals who would likely benefit from interacting with a medical professional. Since microvascular complications of diabetes are very unusual with HbA1c levels <7.0%,³⁷ those

asymptomatic individuals with the higher values in the pre-diabetes range, who might have a value of 6.5% or slightly higher on a laboratory assay, would not be at much risk for these complications, so as long as the values remained below 7.0%. We used a definition of pre-diabetes as HbA1c and FPG ranges of 5.8–6.4% and 110–125 mg/dL, respectively, instead of the ADA definitions of 5.7–6.4% and 110–125 mg/dL. However, had we used the lower ADA definitions, the proportion of individuals identified with pre-diabetes would have been even higher. Finally, the diagnosis of diabetes by an OGTT must be confirmed. However, epidemiological studies routinely use unconfirmed glucose values for their diagnoses.

In conclusion, community screening with HbA1c levels in high risk African Americans and Latinos is effective in identifying those with pre-diabetes and diabetes. This approach would be very helpful for the uninsured and underinsured members of these minority groups.

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Data analysis and interpretation: Davidson, Lee
Manuscript draft: Davidson, Duran, Lee
Statistical expertise: Lee
Acquisition of funding: Davidson
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