Hemoglobin A_{1c} as a Screen for Previously Undiagnosed Prediabetes and Diabetes in an Acute-Care Setting

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OBJECTIVE—Hemoglobin A_{1c} (HbA_{1c}) is recommended for identifying diabetes and prediabetes. Because HbA_{1c} does not fluctuate with recent eating or acute illness, it can be measured in a variety of clinical settings. Although outpatient studies identified HbA_{1c}-screening cutoff values for diabetes and prediabetes, HbA_{1c}-screening thresholds have not been determined for acute-care settings. Using follow-up fasting blood glucose (FBG) and the 2-h oral glucose tolerance test (OGTT) as the criterion gold standard, we determined optimal HbA_{1c}-screening cutoffs for undiagnosed dysglycemia in the emergency department setting.

RESEARCH DESIGN AND METHODS—This was a prospective observational study of adults aged ≥18 years with no known history of hyperglycemia presenting to an emergency department with acute illness. Outpatient FBS and 2-h OGTT were performed after recovery from the acute illness, resulting in diagnostic categorizations of prediabetes, diabetes, and dysglycemia (prediabetes or diabetes). Optimal cutoffs were determined and performance data identified for cut points.

RESULTS—A total of 618 patients were included, with a mean age of 49.7 (±14.9) years and mean HbA_{1c} of 5.68% (±0.86). On the basis of an OGTT, the prevalence of previously undiagnosed prediabetes and diabetes was 31.9 and 10.5%, respectively. The optimal HbA_{1c}-screening cutoff for prediabetes was 5.7% (area under the curve [AUC] = 0.659, sensitivity = 55%, and specificity = 71%), for dysglycemia 5.8% (AUC = 0.717, sensitivity = 57%, and specificity = 79%), and for diabetes 6.0% (AUC = 0.868, sensitivity = 77%, and specificity = 87%).

CONCLUSIONS—We identified HbA_{1c} cut points to screen for prediabetes and diabetes in an emergency department adult population. The values coincide with published outpatient study findings and suggest that an emergency department visit provides an opportunity for HbA_{1c}-based dysglycemia screening.

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There are 26.8 million people with diabetes in the U.S., and by the year 2030, it is estimated to increase to 36 million people (1). Current estimates are that 27% of individuals with diabetes remain undiagnosed, and by the time of diagnosis, there often are microvascular and macrovascular abnormalities found (2–4). Early recognition is important because lifestyle modifications and medications can reduce the incidence of diabetes in people at high risk (5), and the treatment of diabetes can prevent or delay microvascular end-organ complications.

The use of hemoglobin A_{1c} (HbA_{1c}) to diagnose prediabetes and diabetes recently was recommended by the American Diabetes Association (ADA) (6). HbA_{1c} testing has an advantage over glucose-based testing because it does not require fasting, and the test can be performed at any time. Guidelines recommend an HbA_{1c} ≥6.5% to diagnose diabetes and HbA_{1c} between 5.7 and 6.4% for identifying prediabetes. These cutoff values for HbA_{1c} are derived in part from outpatient studies and are based on populations of those not acutely ill at the time of testing (7–9).

Less attention has been given to screening and diagnosing diabetes and prediabetes in acute-care settings such as the emergency department, where blood is routinely drawn to manage acute illness and clinicians are available to interpret the results. The HbA_{1c} test can be quickly performed in many different clinical settings, including the hospital. However, it is not known whether HbA_{1c} thresholds differ between the higher-risk acute-care and the general outpatient populations. The purpose of this study was to determine optimal HbA_{1c}-screening cutoff points for undiagnosed dysglycemia in the emergency department setting using follow-up fasting blood glucose (FBS) and 2-h oral glucose tolerance tests (OGTTs) as the criterion gold standard.

RESEARCH DESIGN AND METHODS

—In this prospective observational study, a convenience sample of adults (aged ≥18 years) with no known history of hyperglycemia who presented to a voluntary hospital emergency department from January 2005 to February 2007 with acute illness were screened for inclusion. Individuals with no known history of elevated glucose and/or diabetes, who had plasma glucose drawn in the emergency department as part of the routine medical work-up and who were willing to return to the general clinical research center after their acute illness was resolved, were eligible. Patients were excluded if they had major acute trauma or burns, metastatic carcinoma, renal failure, hepatic failure, end-stage/debilitating illness, or severe psychiatric illnesses that would preclude participation. Also excluded were patients with acute or chronic pancreatitis, those with sickle-cell disease or trait (which might

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interfere with the assay), those who underwent chemotherapy in the past 6 months, those who used systemic steroids in the past 4 weeks, and those who received intravenous glucose or sympathomimetics before emergency department blood was drawn. The study was approved by the North Shore–Long Island Jewish Institutional Review Board.

After written informed consent was obtained in the emergency department, a detailed medical history was obtained from the patient. HbA_{1c} was measured using the Tosoh G7 (Tosoh Bioscience) high-performance liquid chromatography analyzer. The instrument is certified by the National Glycohemoglobin Standardization Program and International Federation of Clinical Chemistry and Laboratory Medicine, and the interassay and intra-assay coefficient of variation was <3% for HbA_{1c} (http://www.diagnostics.eu.tosohbioscience.com/solutions/hplc+solutions/G7+analyser/). The assay was performed in a National Glycohemoglobin Standardization Program level 1–certified laboratory, which also participates in College of American Pathologists proficiency-testing surveys, including linearity studies. Quality-control testing was performed at the start and end of each batch or shift.

Patients were scheduled to undergo follow-up at the general clinical research center after recovering from their acute illness for an FBS and a 2-h OGTT. Study subjects were instructed to fast overnight for at least 8 h before their testing day and increase carbohydrate intake the day before testing. Diagnostic categories of normal, prediabetes (impaired fasting glucose and impaired glucose tolerance), and diabetes were determined from the results of the FBS and 2-h OGTT using the ADA criteria (10).

Receiver operating characteristic curves were developed, and the area under the curve (AUC) with 95% CIs were determined. Data analyses were conducted for three clinical entities, including individuals with OGTT-diagnosed diabetes compared with those without OGTT-diagnosed diabetes, those with OGTT-diagnosed dysglycemia (either diabetes or prediabetes) compared with those with a normal OGTT, and those with OGTT-diagnosed prediabetes compared with those with a normal OGTT. Optimal HbA_{1c} cutoffs were determined by taking the greatest sum of the sensitivity and specificity for measured HbA_{1c} values among each of the three newly diagnosed groups (diabetes, dysglycemia, and prediabetes). The positive predictive value and negative predictive value were reported for the optimal cutoff values. Additional analyses included in the online Supplementary Data are test-performance data for all HbA_{1c} values for which there was sufficient data. This included positive and negative likelihood ratios and true- and false-positive and true- and false-negative values. SPSS version 16 and XLSTAT software were used to analyze the data.

RESULTS—A total of 2,082 patients consented to participate in the emergency department, and 618 of these patients returned to the general clinical research center, met all inclusion criteria, had full laboratory data for analysis, and were included in the study. The mean age was 49.7 years (±14.9), 343 (55.5%) were male, 47.7% were white, and the mean overall HbA_{1c} was 5.68% (±0.86). Other clinical history is noted in Table 1. The prevalence of diabetes and prediabetes on the basis of emergency department HbA_{1c} testing was 33.0 and 10.2%, respectively, and the prevalence of diabetes and prediabetes on the basis of follow-up glucose-based testing was 31.9 and 10.5%, respectively (Table 2).

The AUC for the group with diabetes was 0.868 (95% CI 0.814–0.922), for the group with prediabetes was 0.659 (0.638–0.679), and for those with dysglycemia was 0.717 (0.704–0.731). Performance criteria, including sensitivity, specificity, and predictive values, also are shown in Table 3. We found the optimal HbA_{1c} cutoff value for diabetes to be 6.0% and that for prediabetes to be 5.7%, and an HbA_{1c} of 5.8% was found to optimally identify individuals with dysglycemia (Table 3). As noted, 42% of patients with an HbA_{1c} of ≥6.0% will have diabetes on the basis of the follow-up OGTT (the positive predictive value), and 97% of patients with an HbA_{1c} <6.0% will not have diabetes (the negative predictive value). In screening for prediabetes, 51.4% of patients with an HbA_{1c} of ≥5.7% will have the disorder on the basis of the follow-up OGTT, and 74.1% of patients with an HbA_{1c} <5.7% will not have prediabetes. In screening for dysglycemia, among those with an HbA_{1c} of ≥5.8%, 66.5% of patients will have the disorder on the basis of the OGTT, whereas 71.3% of individuals with HbA_{1c} values <5.8% will not have dysglycemia.

We also evaluated the performance of an emergency department HbA_{1c} cutoff of 6.5% for identifying individuals with diabetes and found a sensitivity of 54%, a specificity of 96%, and a positive predictive value and negative predictive value of 64 and 95%, respectively. The higher cutoff HbA_{1c} of 6.5% led to fewer false positives than the HbA_{1c} cutoff of 6.0% (20 vs. 70, respectively) but more

Table 1—*Patient characteristics*

Characteristics	
Age (years)	49.7 ± 14.9
BMI (kg/m^2)	29.2 ± 6.83
Sex	
Male	343 (55.5)
Female	275 (44.5)
Ethnicity	
African American	154 (24.9)
White	295 (47.7)
Hispanic	55 (8.9)
Asian/Indian	57 (9.2)
Other*	57 (9.2)
Insurance	
Medicare	75 (12.1)
Medicaid	25 (4.0)
Third party	429 (69.4)
Self-pay	81 (13.1)
Other	8 (1.3)
Hospitalized	
Yes	310 (50.2)
No	308 (49.8)
Time to follow-up (days)	55 ± 56.2
Relative with diabetes†	
Yes	101 (16.3)
Past medical history	
High cholesterol	
Yes	238 (38.5)
No	370 (59.9)
Unknown	9 (1.5)
Hypertension	
Yes	236 (38.2)
No	376 (60.8)
Unknown	4 (0.6)
Coronary artery disease‡	
Yes	109 (17.6)
No	509 (82.4)
Other cardiac§	
Yes	55 (8.9)
No	563 (91.1)
Stroke/transient ischemic attack	
Yes	22 (3.6)
No	596 (96.4)

Data are means ± SD or *n* (%). *N* = 618. *Other = Caribbean, Guyanese, other South American. †Yes = parents or siblings. ‡History of coronary artery disease, coronary artery bypass graft, abnormal cardiac catherization, placement of cardiac stents, history of angina, and/or abnormal stress test. §Other cardiac = congestive heart failure, dysrhythmia, cardiomyopathy, pacemaker, and automatic implantable cardioverter defibrillator.

Table 2—*Determinations on the basis of emergency department HbA$_{1c}$ and follow-up OGTT*

	n (%)
HbA$_{1c}$-based emergency department diagnosis*	
Normal (HbA$_{1c}$ <5.7%)	351 (56.8)
Prediabetes (HbA$_{1c}$ 5.7–6.4%)	204 (33.0)
Diabetes (HbA$_{1c}$ ≥6.5%)	63 (10.2)
HbA$_{1c}$-based emergency department diagnosis using higher-risk cutoffs	
Normal/lower risk (HbA$_{1c}$ <6.0%)	470 (76.1)
High risk for diabetes (HbA$_{1c}$ 6.0–6.4%)	85 (13.8)
Diabetes (HbA$_{1c}$ ≥6.5%)	63 (10.2)
Glucose-based follow-up diagnosis†	
Normal	356 (57.6)
Prediabetes	197 (31.9)
Diabetes	65 (10.5)

*Based on the 2010 ADA guidelines: HbA$_{1c}$ 5.7–6.4% = prediabetes, HbA$_{1c}$ ≥6.5% = diabetes. †Based on FBS and/or 2-h OGTT findings from the general clinical research center follow-up visit.

false negatives (30 vs. 15, respectively). More patients with OGTT-diagnosed diabetes would be missed if the higher HbA$_{1c}$ cutoff of 6.5% is used as the screening threshold. Please see the Supplementary Data for the complete set of HbA$_{1c}$ cutoffs with detailed performance data.

CONCLUSIONS—In an acute-care setting, we found that an HbA$_{1c}$ of 5.7% is the optimal screening cutoff for prediabetes, and 6.0% is the optimal screening cutoff for diabetes. These findings are very similar to a number of previous studies in which individuals from different ethnic and racial groups and geographic regions were tested in outpatient settings. This includes HbA$_{1c}$ cutoffs for prediabetes that have been identified, respectively, from Asian Indian, Chinese, and British populations (11–13). In addition, our findings are consistent with reports from more recent studies that use retinopathy as the criterion for identifying glycemic-related vascular disease (14,15). It is important to note that our HbA$_{1c}$ findings of 5.7% as a screen for prediabetes coincide with recent ADA recommendations for identifying individuals at risk for incident diabetes (6).

Our findings indicating an HbA$_{1c}$ of 6.0% as the optimal diabetes-screening cutoff are consistent with data from other studies that use the FBS or 2-h OGTT to define diabetes (11,12,16–19). The diabetes-screening cutoff that we and others have identified is lower than the diagnostic mark of 6.5% that the ADA guidelines now recommend. The difference in cutoffs can be explained in part by the desired outcome of a screening test to miss fewer people with the target disease, and, therefore, screening cutoffs typically are lower than diagnostic cutoffs. Differences also may occur because of known inconsistencies between the use of glucose and HbA$_{1c}$-based testing to diagnose diabetes because there will be patients with HbA$_{1c}$ values <6.5% who have an FBS ≥126 mg/dL or a 2-h OGTT ≥200 mg/dL (20). Regardless, a diabetes-screening cutoff of 6.0% effectively identifies higher-risk individuals who require referral for additional evaluation and management.

With nearly 120 million emergency department visits annually in the U.S. (21), the emergency department provides a very large pool of all types of individuals who can potentially be screened. Our study concluded that HbA$_{1c}$ cutoffs were similar to patients screened in outpatient settings and suggest that the HbA$_{1c}$ results can be used in a range of clinical settings and that illness acuity also should not preclude screening for dysglycemia. Regarding the prevalence of undiagnosed disease, our study differs from most other studies in that it took place in an acute-care setting and that there was a relatively high frequency of undiagnosed prediabetes and diabetes. In a recent report of the National Health and Nutrition Examination Survey data, the frequency of undiagnosed diabetes using HbA$_{1c}$ was 1.8%, which is lower than in our findings (22). This also differs from data obtained on the inpatient service of an inner-city hospital, where 24% of adults without known diabetes had an HbA$_{1c}$ of ≥6.5% (23). It is possible that the inclusion of patients with a baseline higher diabetes risk profile, as well as acute medical illness, which may be associated with underlying dysglycemia (such as cardiovascular disease), led to a higher frequency of diabetes in the acute-care studies. It also may reflect patients who do not obtain routine outpatient care and, therefore, remain undiagnosed, although in our study, most patients did have some type of medical insurance, suggesting that access to care was less of an issue.

The goal of screening for dysglycemia in the acute-care setting should be earlier diagnosis leading to timely outpatient follow-up with a provider. Although counseling for management of chronic disease may be challenging in acute-care settings, individuals will sometimes show greater interest in their health during times of illness, and opportunities for early diagnosis should not be lost. During a brief discussion, patients with elevated HbA$_{1c}$ could be encouraged to partner with a provider and maintain long-term care as well as attempt lifestyle modifications. The

Table 3—*Optimal HbA$_{1c}$ screening cutoffs for determination of dysglycemia*

	Receiver operating characteristic curve cutoff value (HbA$_{1c}$) (%)	AUC (95% CI)	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Prediabetes	5.7	0.659 (0.638–0.679)	54.8	71.3	51.4	74.1
Diabetes	6.0	0.868 (0.814–0.922)	76.9	87.3	41.7	97.0
Prediabetes/diabetes	5.8	0.717 (0.704–0.731)	56.9	78.9	66.5	71.3

Prediabetes/diabetes = combination of either prediabetes or diabetes.

concept of the "teachable moment" has been demonstrated in the case of smoking cessation in which patients are more likely to quit smoking after health events, such as pregnancy, hospitalizations, or a diagnosis of cancer (24). Such health events represent opportunities for health care providers to educate patients and encourage behavior modifications. Medical triggers are associated with better short- and long-term weight loss, which could be one component of a diabetes intervention (25).

Among limitations for the study, patients were not consecutively screened through the emergency department, and enrollment depended upon the availability of dedicated research associates who generally worked 8-h shifts. Attempts were made to have the investigators rotate through the emergency department during the day, evening, and weekend hours, but there was no overnight coverage. In addition, patients had to sign consent at the time of the emergency department visit to participate and follow-up at the general clinical research center for additional testing. Patients with a previous history of hyperglycemia were excluded from this study; however, some patients may not correctly recall this information, leading to potential misclassification errors. We also did not collect information on the last time patients had outpatient glucose testing before their emergency department visit, and, therefore, we were unable to determine whether there were other recent missed opportunities for diagnosis. As with most laboratory tests, unless the diagnosis is obvious on the basis of clinical presentation, abnormal test findings needs to be repeated at a later time to confirm a diagnosis of prediabetes or diabetes (6).

In summary, optimal HbA_{1c} cutoff values for screening for prediabetes and diabetes in an acute-care setting are similar to cutoffs from populations tested in outpatient settings. There is potential to identify large numbers of emergency department patients with dysglycemia using HbA_{1c}, and an elevated HbA_{1c} should prompt referral for long-term management.

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R.A.S. designed the protocol, supervised the data collection and the data analysis, wrote the final draft of the manuscript, had full access to all of the data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis. K.I., U.T., and R.A.S. analyzed the study data. U.T. and T.E. drafted the manuscript. I.W., K.S., and K.G. obtained study specimens and related clinical data from the patient population.

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