

Diabetes in Urban African-Americans. VI. Utility of Fasting or Random Glucose in Identifying Poor Glycemic Control

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OBJECTIVE — African-Americans have an increased prevalence of both diabetes and diabetes complications, creating an imperative for improved metabolic control. Because American Diabetes Association guidelines recommend that action be taken when HbA_{1c} is >8.0%, but access to rapid-turnaround HbA_{1c} assays remains limited, we tested the utility of fasting and random plasma glucose cutoffs as indicators of HbA_{1c} >8.0%.

RESEARCH DESIGN AND METHODS — Using receiver operating characteristics (ROC) analysis, we evaluated the sensitivity, specificity, and predictive value of fasting and random plasma glucose measurements in identifying an HbA_{1c} >8.0% (fasting *n* = 974, random *n* = 552). The population studied was predominantly African-American, middle-aged, and non-insulin-dependent.

RESULTS — Fasting plasma glucose was a significant indicator of HbA_{1c} >8.0%, both in the whole group and in subgroups for diet, sulfonylureas, and insulin; the corresponding areas under the ROC curve were 0.87, 0.90, 0.87, and 0.84, respectively (all *P* < 0.0001). A fasting plasma glucose cutoff of >9.2 mmol/l (165 mg/dl) provided a sensitivity of 80% and a specificity of 83% for the whole group and a 77% positive predictive value. Random plasma glucose was also a good indicator of HbA_{1c} >8.0%, both in the whole group and in subgroups for diet, sulfonylureas, and insulin; the corresponding areas under the ROC curve were 0.85, 0.91, 0.85, and 0.77, respectively (all *P* < 0.0001). A cutoff >9.8 mmol/l (177 mg/dl) provided a sensitivity of 78% and a specificity of 77% for the whole group and a 78% positive predictive value. Overall, a plasma glucose >11.1 mmol/l (200 mg/dl) identified an HbA_{1c} >8.0% with a predictive value of ~90% if done while fasting and a predictive value of ~80–85% if random. The utility of both fasting and random plasma glucose cutoffs was subsequently confirmed in a prospective study of another 2,309 and 1,396 patients, respectively.

CONCLUSIONS — Although glucose levels cannot replace HbA_{1c} determinations, measurement of fasting or random plasma glucose may be used during a clinic visit to identify poorly controlled type 2 patients with reasonable certainty and allow timely patient education and therapeutic intervention.

Maintaining near-normoglycemia in patients with diabetes has been shown to decrease the risk of microvascular complications for patients with both type 1 (1) and type 2 (2) diabetes. In addition, lower levels of glycemia are associated with a reduced mortality from coronary heart disease in type 2 patients (3,4). These findings have created

an imperative to intensify diabetes therapy in patients presenting with poor glycemic control, with the goal of achieving blood glucose levels as close to normal as possible (4,5). Specifically, recent guidelines published by the American Diabetes Association suggest that action be taken if HbA_{1c} is >8.0% (6). Improving metabolic control is of particular importance in patient popula-

tions enriched with ethnic groups such as African-Americans, who have increased prevalence of both diabetes (7) and diabetes complications (8–10).

While HbA_{1c} remains the main glycemic indicator used to gauge the success of diabetes treatment (1,11,12), the result often is not returned soon enough during patient visits to provide prompt feedback and permit timely adjustment of therapy. Rapid-turnaround HbA_{1c} analyzers are commercially available, but are not yet part of standard office-laboratory equipment in most settings. Accordingly, we studied the value of a single plasma glucose measurement in predicting an HbA_{1c} >8.0%. While the association between plasma glucose and HbA_{1c} has been studied previously (13), we are not aware of any reports focusing on the predictive utility of a single fasting plasma glucose (FPG) or random plasma glucose (RPG) determination in identifying poor glycemic control. To be useful for health care providers in decision-making for intensification of therapy, a test should be both sensitive, to detect most patients with poor glycemic control, and specific, to exclude patients with good glycemic control. Our analysis identifies both fasting and random glucose cutoff values that have such characteristics.

RESEARCH DESIGN AND METHODS

Setting

Patient samples were obtained from the Grady Diabetes Unit, which serves a population that is predominantly African-American and non-insulin-dependent (14), has a high prevalence of diabetes complications (15), and for which management is complicated by both poverty (14) and low literacy (16). Patient care in the Unit is provided by a team that includes both nurse-providers and physicians. New patients are seen at 2-month intervals during the first 6 months and are encouraged to arrive fasting. Plasma glucose is measured at each visit, and HbA_{1c} is determined every 3–4 months. Designation of type 2 diabetes is based on conventional clinical

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Abbreviations: AUC, area under the curve; FPG, fasting plasma glucose; ROC, receiver operating characteristics; RPG, random plasma glucose.

Table 1—Characteristics of patients in FPG study

Characteristic	All patients	Treatment		
		Diet alone	Sulfonylurea	Insulin
n	974	511	126	337
Female (%)	63	73	52	53
African-American (%)	85	90	74	88
Age (years)	54.4 ± 12.8	55.2 ± 12.6	56.8 ± 12.5	52.3 ± 12.8
Type 2 diabetes (%)	83	90	97	78
Diabetes duration (years)	5.4 ± 7.9	3.4 ± 5.9	6.0 ± 6.7	8.3 ± 9.8
Median diabetes duration (years)	0.9	0.6	3.5	5.2
HbA _{1c} (%)	7.9 ± 2.0	7.5 ± 1.9	8.3 ± 2.0	8.4 ± 2.1
Prevalence of HbA _{1c} >8.0% (%)	42	32	50	54

Data are means ± SD unless otherwise indicated.

criteria, such as onset after the age of 40 years, positive family history, presence of obesity, and management without insulin for at least 6 months after diagnosis. Therapy is intensified in the following manner for patients with type 2 diabetes: if control is not satisfactory with diet alone, a sulfonylurea (glipizide or glyburide) is started, and the dosage is increased progressively. When the dosage reaches 20 mg/day, bedtime NPH insulin is added. If bedtime NPH insulin reaches 1 U/kg and satisfactory control is still not achieved, the patient is switched to 70/30 insulin (premixed 70% NPH insulin, 30% regular) twice a day. At each visit, the patients' laboratory test results and type of therapy are entered into a computerized database.

Design

We first studied retrospectively the value of FPG in predicting inadequate glycemic control, which we defined as an HbA_{1c} value >8.0%. We selected all patients presenting between 1991 and 1994 for their 2-month visit who had tests for FPG and HbA_{1c} taken on the same day. We also studied retrospectively the value of RPG measurements in patients who had tests for random nonfasting plasma glucose and HbA_{1c} on the same day. Patients who had been followed for <2 months were excluded, since they were felt not to be in a steady state. Subsequently, the sensitivity, specificity, and positive predictive value of fasting and RPG cutoffs were determined prospectively in patients presenting in 1995–1996.

Both plasma glucose and HbA_{1c} levels were measured in the Grady Memorial Hospital Laboratory. Plasma glucose was measured using an APEC glucose oxidase instrument, and HbA_{1c} was determined by a Biorad high-performance liquid chromatog-

raphy analyzer (normal range for HbA_{1c}, 3.5–6.0%). Receiver operating characteristics (ROC) curves were generated using True Epistat statistical software (Richardson, TX), which also provides a calculated area under the ROC curve. The larger the area under the curve (AUC), the more accurate the test; an associated P value <0.05 was considered statistically significant.

RESULTS

Performance of FPG as an indicator of current HbA_{1c} >8.0%

Between 1 October 1991 and 30 September 1994, 2,716 patients presented for an initial visit to the Grady Diabetes Unit, and 1,415 of these patients presented for a 2-month follow-up visit. Of the 1,415 patients, 974 were given a test for FPG and HbA_{1c} on the same day. The majority of patients were African-American, female, and had type 2 diabetes. The mean age was 54 years, and the mean diabetes duration was 5.4 years. Average HbA_{1c} was 7.9% at the 2-month visit.

The sensitivity and specificity of FPG measurements were tested at 260 values between 2.5 and 35.9 mmol/l (45 and 646 mg/dl, respectively). Figure 1 shows a plot of the sensitivity (true-positive rate) versus 100 – specificity (false-positive rate) of FPG at all cutoffs. The AUC was 0.87 (P < 0.00001). The cutoff value that provided optimal balance of sensitivity and specificity was 9.2 mmol/l (165 mg/dl), with a sensitivity of 80% and a specificity of 83%. The corresponding positive predictive value was 77%.

The performance of FPG in predicting an HbA_{1c} >8.0% was also studied in patient groups stratified according to the type of therapy, i.e., diet alone, sulfonylureas, or

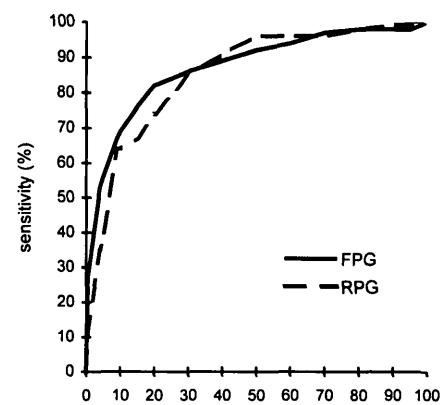


Figure 1—ROC curves for FPG and RPG for detection of current HbA_{1c} >8.0%.

insulin (Figs. 2, 3, and 4). Patient characteristics are shown in Table 1, and data analysis is shown in Table 3. The corresponding areas under the ROC curve were 0.90, 0.87, and 0.84 for patients on diet, sulfonylureas, and insulin, respectively (all P < 0.0001). The FPG cutoffs balancing sensitivity and specificity for all three types of therapy were almost identical—9.2, 9.3, and 9.2 mmol/l, respectively—and were similar to the balanced cutoff of 9.2 mmol/l for the group as a whole. The positive predictive values for these cutoffs were similar across the three groups.

The performance of FPG was also examined in patients with type 1 diabetes. As expected, since all of these patients were insulin treated, the AUC was relatively low at 0.80 (P = 0.0012) compared with the study group as a whole.

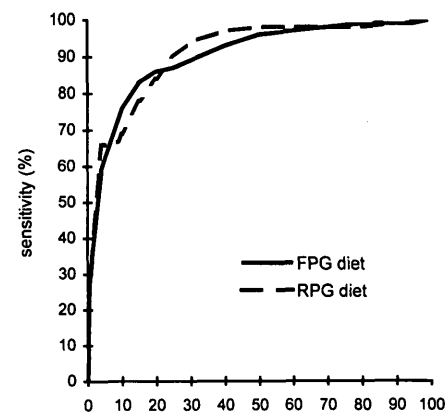


Figure 2—ROC curves for FPG and RPG for detection of current HbA_{1c} >8.0% in patients on diet alone.

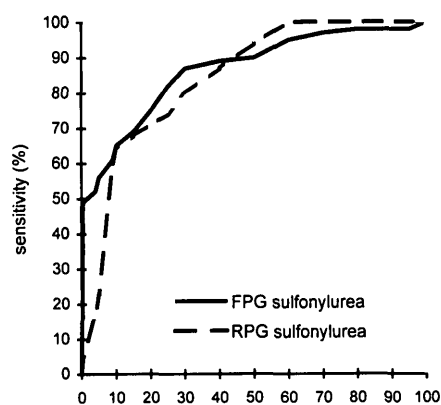


Figure 3—ROC curves for FPG and RPG for detection of current HbA_{1c} >8.0% in patients on sulfonylureas.

Performance of RPG as an indicator of current HbA_{1c} >8.0%

The utility of an RPG measurement was assessed in 552 patients. The patients' characteristics are shown in Table 2 and are comparable to those of patients used in the evaluation of FPG. The sensitivity and specificity of RPG were tested at 254 different cutoffs ranging between 3.1 and 33.9 mmol/l (56–610 mg/dl). Figure 1 shows a plot of the sensitivity (true-positive rate) versus 100 – specificity (false-positive rate) of RPG at all cutoffs. The AUC was 0.85 ($P < 0.00001$), similar to the AUC of FPG (0.87). The cutoff that corresponded to a balance between sensitivity and specificity was 9.8 mmol/l (177 mg/dl), with a sensitivity of 78%, a specificity of 77%, and a positive predictive value of 78%.

The performance of RPG in predicting an HbA_{1c} >8.0% was also studied in patient groups stratified according to the type of therapy, i.e., diet alone, sulfonylureas, or insulin (Figs. 2, 3, and 4). Patient characteristics are shown in Table 2, and data analysis is shown in Table 3. The corresponding areas under the ROC curve were 0.91, 0.85, and 0.77 for patients on diet, sulfonylureas, and insulin, respectively (all $P < 0.0001$). The RPG cutoffs balancing sensitivity and specificity were 9.2, 10.1, and 10.4 mmol/l, respectively. These values were similar but slightly higher than cutoffs for FPG. However, in insulin-treated patients, the area under the ROC curve was higher for FPG than RPG, suggesting that FPG was more accurate in predicting an HbA_{1c} >8.0% (statistical significance could not be tested because FPG and RPG were not available for the same

patient on the same day). In patients with type 1 diabetes, RPG had no clinical utility in predicting an HbA_{1c} >8.0% (AUC = 0.67, $P = 0.09$ [NS]).

Prospective evaluation of the balanced cutoffs for FPG and RPG as indicators of a current HbA_{1c} >8.0%

To test the reproducibility of our results, we evaluated prospectively the utility of the cutoff values of 9.2 mmol/l for FPG and 9.8 mmol/l for RPG in identifying a current HbA_{1c} >8.0%. This analysis was conducted in patients who had a return visit in the period between 1 January 1995 and 31 December 1996 (2 months or more after their initial visit), and excluded patients used in the retrospective analysis. An FPG and an HbA_{1c} were available for 2,309 patients. A cutoff value of 9.2 mmol/l predicted a current HbA_{1c} >8.0% with a sensitivity of 73% and a specificity of 81% and provided a positive predictive value of 75%. Similarly, 1,396 patients had an RPG and an HbA_{1c} available during the same period. A cutoff value of 9.8 mmol/l predicted a current HbA_{1c} >8.0% with a sensitivity of 76%, a specificity of 74%, and a positive predictive value of 75%. These results are comparable to the values found by retrospective analysis.

Analysis of positive predictive value of a cutoff of 11.1 mmol/l (200 mg/dl)

While sensitivity and specificity of a cutoff provide useful information to identify poor glycemic control in a population as a group, positive predictive value is the main determinant of the utility of a cutoff with respect to individual patients. A higher positive predictive value can be achieved if a

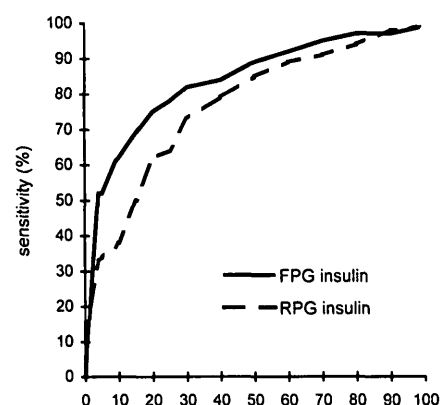


Figure 4—ROC curves for FPG and RPG for detection of current HbA_{1c} >8.0% in patients on insulin.

cutoff with a higher specificity is selected. For instance, choosing an FPG cutoff of 11.1 mmol/l (200 mg/dl) provided a positive predictive value of 88, 89, 88, and 88% for the whole group and in those on diet, sulfonylureas, and insulin, respectively. Similarly, the positive predictive value of an RPG cutoff of 11.1 mmol/l (200 mg/dl) was 83, 79, 87, and 83% for the whole group and those on diet, sulfonylureas, and insulin, respectively. An FPG or RPG >11.1 mmol/l also indicated an HbA_{1c} >7.0% with a positive predictive value of 94 and 93%, respectively. Thus, identification of an FPG or RPG >11.1 mmol/l would permit a practitioner to advise a patient with ~80–90% certainty that a current HbA_{1c} obtained at the time of the visit would be >8.0%—and ~90–95% certainty of HbA_{1c} >7.0%—indicating a high likelihood that therapy should be intensified.

Table 2—Characteristics of patients in RPG study

Characteristic	All patients	Treatment		
		Diet alone	Sulfonylurea	Insulin
n	552	203	152	197
Female (%)	63	67	68	54
African-American (%)	92	96	91	88
Age (years)	56.4 ± 13.0	56.4 ± 14.1	58.0 ± 12.2	55.2 ± 12.5
Type 2 diabetes (%)	84	84	94	77
Diabetes duration (years)	7.1 ± 9.3	4.6 ± 6.3	5.9 ± 7.4	10.7 ± 11.7
Median diabetes duration (years)	2.8	1.9	2.7	6.9
HbA _{1c} (%)	8.5 ± 2.3	7.7 ± 1.9	8.8 ± 2.4	9.2 ± 2.4
Prevalence of HbA _{1c} >8.0% (%)	51	33	56	65

Data are means ± SD unless otherwise indicated.

Table 3—Performance of FPG and RPG in identifying HbA_{1c} >8.0%

	90% sensitivity				Balanced sensitivity and specificity				90% specificity			
	Cutoff (mmol/l)	Sensitivity (%)	Specificity (%)	PPV (%)	Cutoff (mmol/l)	Sensitivity (%)	Specificity (%)	PPV (%)	Cutoff (mmol/l)	Sensitivity (%)	Specificity (%)	PPV (%)
FPG												
All patients	7.4	90	55	59	9.2	80	83	77	10.2	69	90	83
Diet alone	8.0	90	68	57	9.2	82	86	74	9.7	74	90	78
Sulfonylurea	8.6	89	67	73	9.3	79	78	78	10.4	68	89	86
Insulin	7.0	90	50	68	9.2	77	79	81	10.7	64	90	88
RPG												
All patients	8.1	90	61	70	9.8	78	77	78	11.9	64	90	87
Diet alone	8.7	90	77	65	9.2	84	82	70	10.5	73	90	78
Sulfonylurea	8.5	91	60	74	10.1	78	75	80	11.4	67	90	89
Insulin	7.6	90	35	72	10.4	72	73	83	15.1	38	90	88

PPV, positive predictive value.

CONCLUSIONS — In our study, we used ROC analysis to assess the performance of individual glucose levels as a screen for poor glycemic control. Historically, ROC analysis has been used extensively to evaluate the performance of diagnostic laboratory techniques (17) and radiological procedures (18) relative to designated standards. In these assessments, performance is judged based on divergence from the 45° diagonal that connects the 100% true-positive rate to the 100% false-positive rate; this diagonal represents chance alone, and has an AUC of 0.5. More recently, ROC analysis has been extended to the field of diabetes: Tsuji et al. (19) used this technique to compare the performance of FPG, HbA_{1c}, and fructosamine in diabetes screening, and both Engelgau et al. (20) and Borthey et al. (21) used ROC analysis to study the utility of capillary blood glucose in screening large populations for the presence of impaired glucose tolerance and diabetes. Our ROC analysis and predictive value determinations demonstrate that FPG or RPG values can also detect the presence of poor glycemic control in patients with diabetes for whom HbA_{1c} levels are not readily available. Cutoffs of 9.2 mmol/l (165 mg/dl) for FPG and 9.8 mmol/l (177 mg/dl) for RPG constitute reasonably sensitive and specific indicators and performed well when tested both retrospectively and prospectively.

Although not examined by ROC analysis, the association between glucose levels and HbA_{1c} has been noted previously. Pecoraro et al. (13) found a comparable clinical reliability for FPG and glycosylated hemoglobin as indicators of metabolic control in outpatients with type 2 diabetes treated

with diet or sulfonylureas, but reported that FPG was less reliable than HbA_{1c} in type 1 patients and in type 2 patients treated with insulin. Graf et al. (22) reported that FPG was highly correlated with glycosylated hemoglobin (linear regression coefficient of 0.85) in 29 patients with type 2 diabetes treated with diet or sulfonylureas, and Little et al. (23) found a high correlation between HbA_{1c} and both FPG ($r = 0.91$) and 2-h post-load plasma glucose ($r = 0.88$) in Pima Indians screened for diabetes. Another study within that same population showed that there was no significant difference between FPG or 2-h plasma glucose and glycosylated hemoglobin in assessing the association and risk of retinopathy in patients with type 2 diabetes (24). However, Nathan et al. (11) showed that mean blood glucose values are not well identified by either FPG or RPG in a population including significant numbers of type 1 patients. In combination, these reports suggest that FPG or RPG levels are more reliable as glycemic markers in type 2 patients who are managed with sulfonylureas or diet alone compared with patients treated with insulin.

Based on these reports, we were concerned that the modality of diabetes therapy might affect the performance of the screening test. We had anticipated that plasma glucose measurements would have lower utility in insulin-treated patients, in whom a single plasma glucose value might reflect the effect of exogenous insulin at a single point in time rather than the patients' overall metabolic control. However, our results indicate that insulin-treated patients exhibit optimal FPG cutoffs similar to those of patients treated with sulfonylureas or with diet alone, with similar AUCs. In contrast,

the performance of RPG in screening for poor control was inferior in patients treated with insulin compared with patients treated with diet alone or with sulfonylureas, as judged by the area under the ROC curve in each subpopulation. Furthermore, RPG had no clinical utility in identifying poor control in patients with type 1 diabetes.

Recent reports by Mazze et al. (25) and Marrero et al. (26) indicate that the availability of HbA_{1c} data during patient encounters may make a difference in diabetes treatment. However, in our clinic and many others, HbA_{1c} data are not available during patient visits. Based on our results and a 40–50% prevalence of poor glycemic control, intensifying therapy would be appropriate in 80–90% of patients presenting with an FPG or RPG >11.1 mmol/l. For such patients, management could be intensified during the clinic visit (revised diet or medication) rather than waiting until the HbA_{1c} level is available a few days later and having to ask the patient to return for intensification of management. Moreover, difficulty in contacting patients and failure of patients to return can pose barriers to adjustment of therapy after patients have left the clinic.

It should be emphasized that a cutoff balancing sensitivity and specificity may not be optimal for individual patients. For instance, a high indicator specificity (avoiding false-positives) might be particularly important in the management of unstable or brittle patients, for whom an inappropriate increase in insulin dosage could result in severe hypoglycemia (1). In contrast, a higher sensitivity might be desirable in stable patients with type 2 diabetes, since recent studies suggest that hypoglycemia tends to be mild and infrequent in this

group (27–29), and intensive therapy can decrease microvascular complications in such patients (2).

Finally, our analysis excluded, and therefore may not apply to, newly diagnosed patients with diabetes, who may not be in steady state. Indeed, it has been shown that glucose levels can fall rapidly during outpatient management of obese African-Americans who present with diabetic ketoacidosis (30), while HbA_{1c} levels would be expected to lag behind (2). Also, our results apply to plasma glucose measurements only and not necessarily to blood or serum glucose measurements. In addition, our patient population is largely African-American and non-insulin-dependent, with a female majority. Although these factors might preclude the generalization of our results to other groups with type 2 diabetes, we feel that the basic pathophysiology should be comparable in other populations with a similar high prevalence of elevated HbA_{1c}. However, the greater instability of plasma glucose levels in type 1 patients may weaken the relationship between glucose levels and HbA_{1c}. Therefore, we do not recommend that our findings be used in the management of type 1 patients.

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