Screening for Diabetes Mellitus in Adults

The utility of random capillary blood glucose measurements

Michael M. Engelgau, md, ms
Theodore J. Thompson, ms
Philip J. Smith, phd
William H. Herman, md, mph
Ronald E. Aubert, phd, msph
Elaine W. Gunter, bs, mt (ascp)
Scott F. Wetterhall, md, mph
Edward S. Sous, md
Mohamed A. Ali, md

OBJECTIVE — Because half of the people with non-insulin-dependent diabetes mellitus (NIDDM) are undiagnosed and because near-normal glycemic control can prevent diabetic complications, we evaluated the use of field-based random capillary blood glucose measurement as a screening test for NIDDM.

RESEARCH DESIGN AND METHODS — A cross-sectional sample of 828 Egyptians ≥20 years of age underwent both a random capillary blood glucose measurement performed with a portable reflectance meter in the field and an oral glucose tolerance test in the laboratory. The sensitivity and specificity of random capillary blood glucose measurements in predicting the presence of NIDDM were evaluated.

RESULTS — Multivariate analyses showed that the screening test performed better when subjects had eaten shortly before the test (area under receiver operating characteristic curve, 0.87 for a 1-h postprandial period compared with 0.69 for an 8-h postprandial period) and that the optimal capillary blood glucose cutoff points to define a positive test increased with age. For a postprandial period of 1 h, cutoff points of 115 mg/dl for individuals 30 years of age and 140 mg/dl for those 75 years of age yielded similar performance characteristics (sensitivity 82% and specificity 78% for those 30 years old; sensitivity 81% and specificity 80% for those 75 years old).

CONCLUSIONS — Adjusting random capillary blood glucose measurements for the postprandial period and using age-specific cutoff point values can improve performance of the screening test.

From the Epidemiology and Statistics Branch, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion; the National Center for Prevention Services (P.J.S.); the Epidemiology Program Office (S.F.W.); and the National Center for Environmental Health (E.W.G.), Centers for Disease Control and Prevention, Atlanta, Georgia; and the Diabetes Institute, Ministry of Health (E.S.S., M.A.A.), Cairo, Egypt.

Address correspondence and reprint requests to Michael M. Engelgau, MD, MS, Division of Diabetes Translation, Mail Stop K-10, Centers for Disease Control and Prevention, 4770 Buford Hwy. NE, Atlanta, GA 30341-3724.

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CV, coefficient of variation; NIDDM, non-insulin-dependent diabetes mellitus; ROC, receiver operating characteristic.

Screening asymptomatic individuals may be useful for identifying undiagnosed non-insulin-dependent diabetes mellitus (NIDDM). Studies of the screening performance of capillary glucose measurement with a reflectance meter have used various protocols including individuals in fasting, random, and oral glucose–loaded states, populations with a large proportion of individuals who have glucose intolerance, and various analytic methods (1–7). The purpose of this study was to characterize the performance of a field-based diabetes screening test that used random capillary blood glucose values, measured with a portable reflectance meter, and self-reported information about the postprandial period.

RESEARCH DESIGN AND METHODS

During the Diabetes in Egypt Project between July 1992 and October 1993, households were sampled from census listings and one person ≥20 years of age was chosen from each. Informed consent was obtained from all participants. All individuals with a history of diabetes were excluded from this analysis.

Field workers trained in interview procedures and the use of portable reflectance meters collected information about age, sex, diabetes status, diabetes medication use, family history of diabetes, and the time since ingestion of any food or drink except water (hereafter referred to as the postprandial period). A capillary whole blood glucose measurement was then performed with a portable reflectance meter (One Touch II, Lifescan, Milpitas, CA). Quality control testing of the meters was performed daily by field workers (coefficient of variation [CV] for low-range [41–65 mg/dl] measurements was 3.5%; for middle-range [84–126 mg/dl] measurements, 4.5%; and for high-range [264–391 mg/dl] measurements, 7.2%). The household visit typically occurred in the late afternoon after the midday meal but before the evening meal.

Within 1 week after the household visit, participants fasted for 10–14 h and came to the laboratory in the morning. Fasting glucose and oral glucose tolerance tests were performed. Diabetes was diagnosed according to World Health Organization criteria (8): either a fasting venous serum glucose level ≥140 mg/dl or a 2-h value ≥200 mg/dl after a 75-g oral glucose load. Serum glucose was measured by the glucose oxidase method (CV 3.8%) with a dry chemistry analyzer (Kodak DT-60, Eastman-Kodak, Rochester, NY).

Receiver operating characteristic (ROC) curves, which characterize the relationship between the true-positive rate (sensitivity) and the false-positive rate (1 − specificity) as the cutoff point value of a positive screening test varies, served to analyze screening test performance (9). The capillary glucose cutoff point categories selected for the ROC curve analyses were ≥80, ≥85, ≥90, ≥95, ≥100, ≥105, ≥110, ≥115, ≥120, ≥125, ≥130, ≥140, ≥150, ≥160, and ≥200 mg/dl. We performed multivariate analyses with SAS (10) using the proportional odds model for ordinal data (11). The probability that the capillary glucose category (outcome variable) correctly classified people using the selected cutoff point category was modeled as a function of the covariates (diabetes status, sex, and family history of diabetes as categorical variables; postprandial period and age as continuous variables). Both main effects and interaction effects were tested. All covariates in the reduced model had a corresponding $P < 0.01$.

RESULTS— The study population consisted of 828 subjects. The mean age was 46.6 years (range: 20–90 years), 40% were men, and 40% had a family history of diabetes. Overall, 10.4% (86 of 828) had previously undiagnosed diabetes. The postprandial period ranged from 1 h to >9 h. The mean capillary glucose measurements were higher for those with diabetes at all postprandial periods.

The multivariate model using capillary glucose cutoff point categories showed that age, postprandial period, and diabetes status were significant covariates ($P < 0.01$). The final model also included a diabetes status–postprandial period interaction term. Distinct ROC curves for the various levels of a variable occurred only when the variable had a significant interaction term with diabetes status. Thus, each postprandial period defined an ROC curve that was unchanged by age or other variables. The area under the ROC curve decreased as the postprandial period increased: 0.87 for a 1-h postprandial period before the glucose capillary measurement, 0.85 for 2 h, 0.83 for 3 h, 0.81 for 4 h, 0.78 for 5 h, 0.75 for 6 h, 0.72 for 7 h, and 0.69 for 8 h.

The location of cutoff points on each ROC curve was dependent on both postprandial period and age. As the postprandial period increased, lower cutoff point values shifted to higher positions on the ROC curve for that postprandial period. Thus, a lower cutoff point at a long postprandial period achieved the optimal sensitivity and specificity (where the sum of the sensitivity and specificity is at a maximum) that a higher cutoff point after a short postprandial period did (Table 1). As age increased, the cutoff point values were shifted to higher positions on each age-specific postprandial period–specific ROC curve. Therefore, a higher cutoff point was needed in older individuals than in younger individuals to yield a comparable sensitivity and specificity.

The optimal cutoff point for those who fasted 1 h ranged from 115 mg/dl for 30-year-olds to 140 mg/dl for 75-year-olds (Table 1). Cutoff points for the postprandial periods of 1–6 h over the range of ages, with a sensitivity of near 90%, had a specificity that ranged from roughly 35 to 60%; at a specificity of ≥90%, the sensitivity ranged from roughly 35 to 70%. Predictive positive values for each cutoff point, calculated for a hypothetical population with 5% prevalence of undiagnosed NIDDM, decreased as the postprandial period increased and ranged from 7 to 11% at a sensitivity of 90%, 10 to 18% at the optimal cutoff point, and 17 to 26% at 90% specificity.

Intermediate age-specific and postprandial period–specific cutoff points can be estimated from Table 1. For example, the optimal cutoff point (i.e., both sensitivity and specificity of roughly 80%) for a 37-year-old individual who had a postprandial period of 1 h would roughly be the midpoint between a 30-year-old's cutoff point of 115 mg/dl and a 45-year-old's cutoff point of 125 mg/dl, or ~120 mg/dl.

CONCLUSIONS— In this study, we found that postprandial period and age significantly affect the performance of a random capillary blood glucose measurement used as a screening test for diabetes. We found that better performance is achieved with shorter postprandial periods than with longer postprandial periods and that as the postprandial period increases, the cutoff point needed to yield a given level of performance decreases. We also found that as age increases, cutoff points increase for a given level of performance. Other risk factors for diabetes, such as obesity and hypertension, were also examined (data not shown) and did not affect screening test performance.

Other studies have evaluated screening properties of random capillary blood glucose measurement using a reflectance meter. Although the effects of postprandial period and age were not characterized, the reported performance is similar to what we found. One study found a sensitivity of 69% and specificity of 94% at a cutoff point of 144 mg/dl, while another found a sensitivity of 80% and specificity of 80% at a cutoff point of 130 mg/dl (2,6). A recent evaluation of fasting capillary blood glucose measured with a reflectance meter found that a cutoff point of 100 mg/dl yielded a sensitivity of 87% and specificity of 73% (1).

Random blood glucose levels depend on several factors, including age (12), postprandial period (8,13), usual diet (14), and type of meal last consumed. Like Andres (15), who developed age-

Table 1—*Properties of capillary glucose screening tests near 90% sensitivity, at the optimal cutoff point (where the sum of sensitivity and specificity is at a maximum), and near 90% specificity for detecting diabetes in the study population, by age and postprandial period*

		Sensitivity 90%				Optimal				Specificity 90%			
Age (years)	PP period (h)	Cutoff point (mg/dl)	Sens	Spec	PPV	Cutoff point (mg/dl)	Sens	Spec	PPV	Cutoff point (mg/dl)	Sens	Spec	PPV
30	1	≥105	92 (84–96)	59 (52–66)	11	≥115	82 (69–91)	78 (73–83)	16	≥130	66 (48–80)	90 (86–92)	26
	2	≥100	90 (83–94)	59 (54–65)	10	≥110	78 (66–86)	79 (75–83)	16	≥120	63 (49–76)	89 (85–91)	23
	3	≥90	91 (86–94)	51 (46–56)	9	≥105	75 (65–83)	78 (74–82)	15	≥115	54 (43–66)	90 (87–92)	23
	4	≥85	90 (85–94)	49 (43–54)	9	≥100	72 (62–80)	77 (73–81)	14	≥110	50 (39–61)	90 (87–92)	21
	5	≥80	90 (84–94)	44 (38–50)	8	≥90	76 (65–83)	69 (64–74)	11	≥105	48 (36–60)	88 (85–90)	20
	6	≥80	83 (74–90)	52 (46–59)	8	≥85	75 (63–85)	65 (59–71)	10	≥95	35 (23–49)	91 (89–94)	17
45	1	≥110	92 (85–96)	58 (51–64)	10	≥125	81 (67–89)	80 (74–84)	18	≥150	61 (44–76)	91 (88–94)	26
	2	≥105	91 (85–95)	58 (53–62)	10	≥115	80 (69–87)	77 (73–81)	15	≥130	62 (49–74)	89 (86–91)	23
	3	≥95	92 (88–95)	49 (45–53)	9	≥110	76 (67–83)	77 (74–80)	15	≥125	52 (41–62)	91 (89–93)	23
	4	≥90	90 (86–94)	48 (44–52)	8	≥105	73 (65–81)	76 (72–79)	14	≥120	46 (36–56)	91 (89–93)	21
	5	≥85	90 (85–93)	44 (40–49)	8	≥100	71 (61–80)	74 (70–77)	13	≥115	39 (29–50)	92 (90–93)	20
	6	≥80	90 (84–94)	40 (34–44)	7	≥95	67 (54–78)	74 (69–78)	12	≥110	36 (25–50)	91 (88–93)	17
60	1	≥115	92 (85–96)	59 (52–56)	11	≥130	83 (70–91)	77 (71–83)	16	≥160	65 (47–79)	90 (86–93)	25
	2	≥110	90 (83–94)	60 (54–66)	11	≥120	81 (71–88)	75 (70–80)	15	≥140	61 (47–73)	90 (86–92)	24
	3	≥100	92 (88–95)	47 (42–52)	8	≥115	75 (66–82)	78 (74–82)	15	≥130	56 (45–66)	89 (87–92)	21
	4	≥95	90 (85–93)	49 (44–54)	8	≥110	71 (62–79)	77 (73–81)	14	≥125	46 (36–56)	91 (88–93)	21
	5	≥90	89 (83–93)	47 (42–52)	8	≥105	70 (59–78)	75 (71–79)	13	≥120	41 (31–52)	91 (89–93)	19
	6	≥85	88 (81–93)	43 (37–49)	8	≥100	68 (56–79)	72 (67–77)	11	≥115	35 (24–48)	91 (89–93)	17
75	1	≥120	92 (85–96)	59 (50–67)	11	≥140	81 (67–90)	80 (73–86)	18	≥160	71 (54–83)	87 (81–91)	22
	2	≥110	92 (87–96)	53 (46–60)	9	≥130	76 (65–85)	80 (75–85)	17	≥150	60 (47–73)	90 (85–93)	24
	3	≥105	91 (86–94)	52 (45–58)	9	≥120	75 (66–83)	78 (73–82)	15	≥140	52 (41–63)	91 (87–93)	23
	4	≥100	90 (85–93)	50 (43–56)	9	≥110	77 (67–84)	72 (66–77)	13	≥130	48 (37–58)	90 (87–93)	20
	5	≥90	91 (87–95)	40 (34–46)	7	≥105	75 (66–83)	69 (63–75)	11	≥125	39 (29–51)	91 (89–94)	19
	6	≥85	91 (78–92)	36 (29–43)	7	≥100	74 (62–84)	66 (59–72)	10	≥120	35 (24–49)	91 (88–94)	17

PP, postprandial; Sens and Spec, sensitivity and specificity expressed as a percentage (95% confidence interval); PPV, predictive positive value expressed as a percentage for a population with 5% prevalence of undiagnosed diabetes.

specific 2-h post–oral glucose tolerance test blood glucose levels, we developed age-specific cutoff points that yield similar levels of test performance. We noted that the difference in blood glucose level between those with and those without diabetes was greater for short postprandial periods (data not shown), and therefore, it is not surprising that performance was better with short postprandial periods.

Although the level of carbohydrate consumed in the diet before an oral glucose challenge affects the postprandial blood glucose level (14), neither the type of diet consumed during the days preceding the screening test nor the type and quantity of the most recently consumed food or beverage was available. This type of information is extremely difficult to obtain reliably. The extent to which this information would improve performance is unclear. Because most individuals were screened in the mid-afternoon, the previous meal would have been the one consumed at midday, which can be a highly variable meal in Egypt.

The American Diabetes Association (16) recommends screening for diabetes in selected individuals who have risk factors for NIDDM and provides guidelines for screening procedures. However, the performance of these procedures has not been rigorously evaluated. While our estimates of test performance using the model do vary, they should be of great use to screening programs. In addition, using the estimated prevalence of individuals with undiagnosed NIDDM in the population to be screened and the screening test performance level, programs can calculate the expected predictive positive value, as we have done in Table 1.

Capillary glucose measurements and age-specific cutoff point values may be useful for community-based screening because the testing procedure is easier for the field worker, is more acceptable for participants (finger stick versus venipuncture), is more convenient (performed in the field versus in the laboratory), requires fewer resources, and can be tailored to each person (by use of self-reported age and postprandial period) to achieve optimal performance. This diabetes screening technique could allow for better use of laboratory-based oral glucose tolerance tests and other blood glucose testing.

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