Validation of a Type 2 Diabetes Screening Tool in Rural Honduras

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OBJECTIVE — To validate a low-cost tool for identifying diabetic patients in rural areas of Latin America.

RESEARCH DESIGN AND METHODS — A regression equation incorporating postprandial time and a random plasma glucose was used to screen 800 adults in Honduras. Patients with a probability of diabetes of ≥20% were asked to return for a fasting plasma glucose (FPG). A random fifth of those with a screener-based probability of diabetes <20% were also asked to return for follow-up. The gold standard was an FPG ≥126 mg/dl.

RESULTS — The screener had very good test characteristics (area under the receiver operating characteristic curve = 0.89). Using the screening criterion of ≥0.42, the equation had a sensitivity of 74.1% and specificity of 97.2%.

CONCLUSIONS — This screener is a valid measure of diabetes risk in Honduras and could be used to identify diabetic patients in poor clinics in Latin America.

Diabetes Care 33:275–277, 2010

As the global prevalence of diabetes increases, developing countries will experience 80% of the burden (1). A recent study (2) found that 7.8% of adults in the capital city of Honduras had diabetes and 42% of them were unaware of their condition.

There is little consensus about the most cost-effective means of screening for diabetes in developing countries (3). The oral glucose tolerance test is difficult to implement, and laboratory-based A1C testing is unavailable in many areas (4). Screening tools have been developed that combine risk factor information into an overall estimate of patients' probability of disease (4–8). Models limited to information about patient demographics, BMI, and blood pressure often show only moderate test specificity. In contrast, a screening algorithm that incorporates random plasma glucose test results and postprandial time has shown excellent predictive accuracy (4,5). Additional validation is important to ensure that the instrument has adequate sensitivity and specificity in Latin America, given differences in diet, body structure, and other risk factors in the region. The purpose of the current study was to validate this diabetes-screening tool among patients seeking medical care in Honduras.

RESEARCH DESIGN AND METHODS

The study was conducted in a primary care clinic serving low-income patients in central Honduras. Eight hundred adult patients, who were not pregnant, did not have a heart attack in the prior 3 months, and had no diagnosis of diabetes were recruited. The study was approved by our university institutional review board.

Initial screening

Participants completed a face-to-face interview and a random plasma glucose test using a fingerstick blood sample and the Accu-Chek Aviva point-of-care capillary glucose meter. The survey included questions regarding sociodemographic and family history risk factors (9). Blood pressure and BMI (kg/m^2) were recorded with weight, which was measured while the patient wore light clothing and no shoes. Postprandial time was recorded as the number of hours since the participant last ate or drank anything other than water. Survey responses and clinical measurements were used to calculate their probability of diabetes using the following equation (4): p (diabetes) = $1/[1 + \exp(-X)]$, where $X = -10.0382 + 0.0331 \times$ (age in years) $+ 0.0308 \times$ (random plasma glucose in mg/dl) $+ 0.25 \times$ (self-reported postprandial time assessed in hours) $+ 0.562$ (if female) $+ 0.0346 \times$ (BMI).

Follow-up fasting glucose test

All participants with an equation-based probability of diabetes ≥20% were asked to return for evaluation at least 24 h after their initial visit, having fasted for at least 8 h. Every fifth participant with a probability of diabetes <20% also was asked to return for follow-up. During follow-up visits, fasting plasma glucose (FPG) was measured using 10 μl of capillary blood derived from a fingerstick and the HemoCue 200 analyzer. Patients were considered to have diabetes if their FPG was ≥126 mg/dl (10). These patients were referred for further evaluation.

Analysis

To validate the prognostic significance of the screening equation and identify the optimal cut point for determining a positive screening test, a maximum-likelihood receiver-operating characteristic (ROC) curve was fit using STATA's ROCFIT procedure (11). Positive and negative predictive values were then calculated across a range of cut points.

We assigned all 800 recruited patients into two levels of diabetes risk, us-

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Received 3 June 2009 and accepted 5 November 2009. Published ahead of print at http://care.diabetesjournals.org on 16 November 2009. DOI: 10.2337/dc09-1021.

ing their initial screening equation–based diabetes probability and FPG test result (if completed). Within low- and high-risk groups, we differentiated individuals whose risk was confirmed based on an FPG and those whose risk was based solely on their initial screening. Between and within groups, we examined the characteristics of patients associated with the likelihood of returning for an FPG test.

RESULTS

Patient recruitment and follow-up

A total of 800 patients participated (266 men and 534 women). Mean age was 38.5 years, and the average monthly household income was USD 319. Of the original sample, 8.4% were identified as having a ≥20% risk of diabetes and were asked to return for FPG testing. The remaining patients had <20% risk, and of these 133 (20%) were asked to return for follow-up. Two-thirds (66.5%) of all patients who were asked to return for follow-up returned, with no difference in the proportion returning based on their estimated probability of diabetes. Among high-risk patients, those who failed to return were more likely to be older, male, have little formal education, and have seven or more children.

Test performance

Using FPG ≥126 mg/dl as the gold standard, the screener had very good predictive accuracy with an overall area under the curve (AUC) of 0.89 (Fig. 1). Classification accuracy was maximized using a probability of diabetes of 0.42. Using that criterion, 74.1% of all patients with diabetes confirmed by FPG were correctly classified, as were 97.2% of patients without diabetes (a false-positive rate of 3%). Assuming a diabetes prevalence of 7.4% (the best estimate based on this sample), the test had a positive predictive value of 68% and a negative predictive value of 98%.

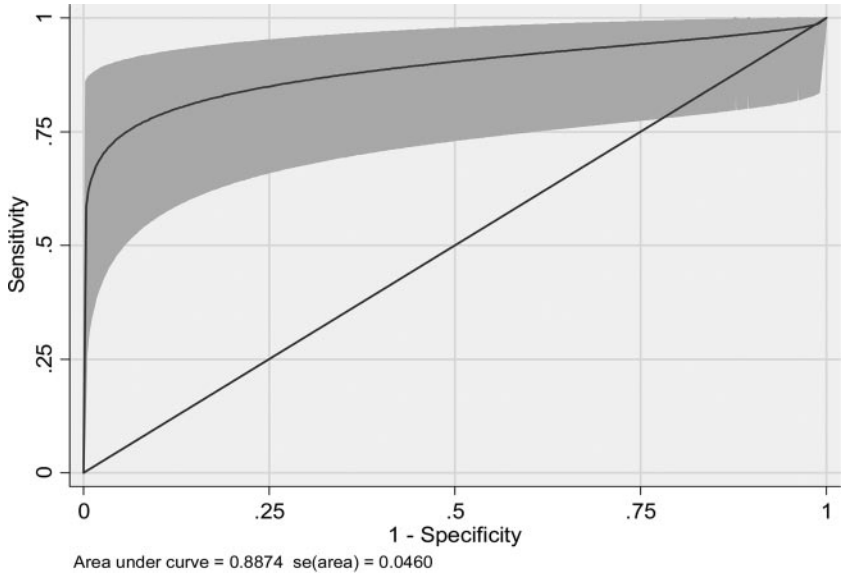

Figure 1—*Receiver operating characteristic curve. The gray area represents the 95% confidence band. The diagonal reference line defines the points where the test would predict diabetes no better than chance. Sensitivity and specificity of the screening instrument were calculated using an FPG of ≥126 mg/dl as the gold standard.*

CONCLUSIONS— In Latin America, diabetes often goes undiagnosed until a major health event occurs (1–3,12–14). A formula-based screening tool that includes a random plasma glucose, information about postprandial time, and basic information about other risk factors is a viable approach to identify most patients with diabetes in Honduras.

Comparisons of the AUC in the current study (0.89) with prior studies using the same screening tool show that the screener performed at least as well in Honduras as in other parts of the world (4,5). However, the cut point for identifying probable diabetes has varied across studies. In the current study, a probability of 0.42 was associated with a sensitivity of 74.1% and specificity of 97.2%. In comparison, a suggested cut point of 0.2 in Egypt was associated with a somewhat lower sensitivity (65%) and roughly equivalent specificity of 96% (4). In the U.S., a cut point of 0.38 was associated with poorer sensitivity (53%) and specificity (89%) (5). These differences in cut points and test performance suggest that further evaluation in Latin America would be useful, especially in studies using other diagnostic tests such as the 2-h plasma glucose test, oral glucose tolerance test, or A1C. Especially since clinical guidelines recommend repeating FPG on a second day for diagnosing diabetes, other studies with different gold standards are warranted.

High-risk patients who failed to return for FPG testing had increased travel distance, lower educational attainment, and larger family size, suggesting that the screener may be an effective adjunct to confirmatory measures such as an FPG, reaching more patients with diabetes and, in particular, those at heightened risk for poor outcomes. While further validation in Latin America is important, this screener should be considered for use throughout the region.

Acknowledgments— This research was funded jointly by the University of Michigan School of Public Health Global Health Summer Internship Program, the Michigan Diabetes Research and Training Center (National Institutes of Health [NIH] no. DK020572), and the Michigan Institute for Clinical and Health Research (NIH no. UL1RR024986). J.D.P. is a Veterans Affairs Senior Research Career Scientist. E.C.M. and A.E.A. were supported by a grant from the Center for Integrative Approaches to Health Disparities (1P60MD00249-01).

No potential conflicts of interest relevant to this article were reported.

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