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Application of the Revised American Diabetes Association Criteria for the Diagnosis of Diabetes in a Canadian Native Population

Recently, the American Diabetes Association (ADA) presented revised criteria for the diagnosis of diabetes in epidemiologic studies (1). These criteria de-emphasize the use of the oral glucose tolerance test (OGTT) and establish a lower fasting plasma glucose (FPG) level for the diagnosis of diabetes (≥7.0 mmol/l) (1). Additionally, the ADA has recognized "an intermediate group of subjects whose glucose levels, although not meeting criteria for diabetes, are nevertheless too high to be considered altogether normal" (1). This group has been termed impaired fasting glucose (IFG) and is defined as having an FPG ≥6.1 and <7.0 (1).

We evaluated the performance of these new diagnostic criteria against established World Health Organization (WHO) (2) criteria from a recently completed population-based epidemiologic diabetes prevalence and risk factor survey in a Native Canadian community (3,4). The methodology of this project has been described in previous publications (3,4). In summary, 728 of 1,018 (72%) eligible members of the community aged 10–79 years provided fasting blood samples for glucose after an 8- to 12-h overnight fast. A 75-g OGTT was administered, and a second sample for glucose was drawn after 120 min. Diabetes and impaired glucose tolerance (IGT) were diagnosed according to WHO criteria (2). Individuals with missing fasting or 2-h glucose values (2.9%) or with physician-diagnosed diabetes at the time of the survey (9.9%) were excluded from the present analysis. The revised criteria for diabetes were evaluated against WHO diabetes criteria as the gold standard. Additionally, the new IFG category was evaluated against IGT (as defined by WHO [2]). Standard methods (5,6) were used to calculate diagnostic performance indicators and to construct a receiver operator characteristic (ROC) curve for diabetes over a range of FPG cut points.

Prevalence of newly diagnosed diabetes based on the revised criteria was 6.1%, slightly lower than that based on the WHO system (7.1%). Prevalence of IFG, on the other hand, was estimated to be 7.1%, a notable decline compared with the prevalence of IGT (10.3%). Sensitivity (Se) for detecting diabetes using FPG ≥7.0 mmol/l was moderately high (68.0%), as was the predictive value of a positive test (PV^+) (79.1%) in this population. Both specificity (Sp) and negative predictive value (PV^-) were high (98.5 and 97.3%, respectively). The new IFG category did not perform as well with regard to the detection of IGT, with an Se of only 17.8% and PV^+ of 26.0%. Sp (93.4%) and PV^- (89.7%) were also lower than for diabetes. The ROC curve for diabetes (Fig. 1) indicates that Se is low (<60%) and Sp is very high (>99%) at FPG cut points above 7.3 mmol/l. As the FPG cutoff level is reduced, Se increases with little reduction in Sp until an FPG of 6.6 mmol/l (Se = 78.0%, Sp = 97.9%). Thereafter, there is a more gradual increase in Se with sharp declines in Sp (e.g., at FPG = 5.7 mmol/l, Se = 86.0%, and Sp = 76.2%).

We conclude that the revised ADA criteria perform at an acceptable level for the diagnosis of diabetes in a Canadian aboriginal population. Criteria for a diagnosis of IFG, on the other hand, do not appear to be useful in identifying individuals with

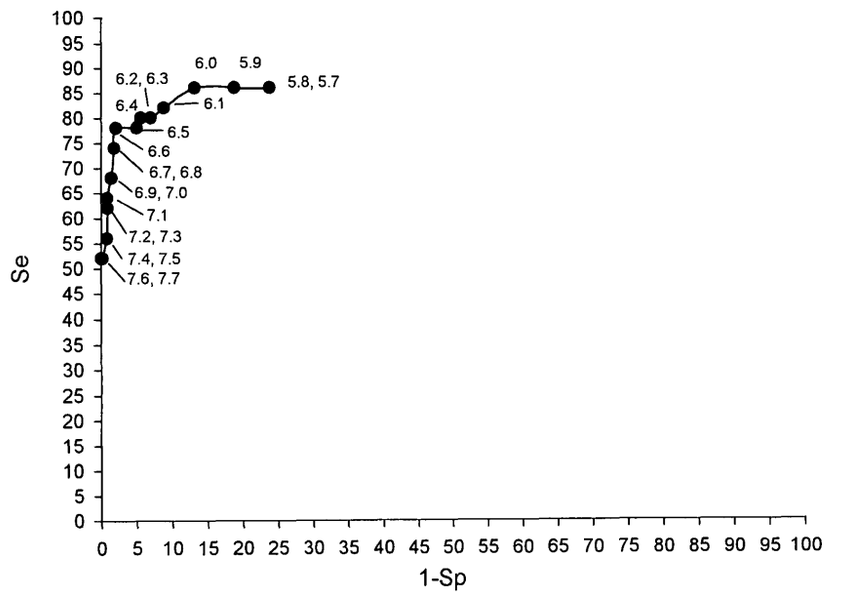

Figure 1—*ROC curve describing the relationship between Se and Sp over the range of FPG cut points.*

intermediate glucose intolerance; this concept, however, is controversial, and requires further research (7).

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Use of a Laser Skin Perforator for Determination of Capillary Blood Glucose Yields Reliable Results and High Patient Acceptability

It is recommended that capillary blood glucose (CBG) determination be performed three to four times daily in patients with type 1 diabetes and at an undetermined frequency in those with type 2 diabetes (1,2). There are limitations to the routine practice of home CBG monitoring, however, including high cost, variable reliability of the procedure, possible exposure to blood-borne infection, and pain (3). Because up to 67% of patients with diabetes do not monitor their CBG levels, technologies and strategies that specifically address these limitations are needed (4).

The Lasette is a flashlamp-pumped erbium:YAG (yttrium aluminum garnet) solid-state laser skin perforator that has recently been approved for the attainment of capillary blood samples in the U.S. This report summarizes two studies that used the Lasette for attainment of CBG and hematocrit samples, compared with standard stainless steel lancets. We hypothesized that use of the Lasette for capillary blood sampling would result in reliable CBG determination, high patient acceptability, and rapid wound healing. The results demonstrate that use of the Lasette results in CBG and hematocrit determination equivalent to that obtained by standard methodology.

Two similar protocols were performed at two different hospitals in Albuquerque, New Mexico: the University of New Mexico Health Sciences Center (study 1) and Lovelace Medical Center (study 2). Both studies entailed capillary blood sampling from the fingertips of 100 patients with type 1 or type 2 diabetes. Blood was sampled without respect for the time of last meal ingestion from a randomly selected finger of the nondominant hand using the Lasette (Cell Robotics, Albuquerque, NM) and from an adjacent finger using a standard stainless steel lancet (Ultrafine Lancet; Becton Dickinson, Franklin Lakes, NJ). The order of sampling was also randomized. Inclusion criteria encompassed adult patients receiving treatment for diabetes, and patients with a history of blood dyscrasia, hepatitis B, or human immunodeficiency virus positivity were excluded. Blood was analyzed for CBG and spun hematocrit in both studies. Blood was applied first to the CBG strip and then collected into capillary tubes for hematocrit determination. If an insufficient sample was obtained after the first attempt, repeated attempts were made. The total amount of blood sampled was ~200 µl in study 1 and 100 µl in study 2.

In study 1, two attempts to obtain capillary blood with the Lasette were made at an energy setting of 400 mJ. After sample collection was completed, subjects completed a survey that assessed attitudes about both sampling methods, and subjects were contacted by telephone 48 h after completing the study to confirm wound healing. In study 2, subjects received a graded exposure to the laser in which a first attempt was made with an energy setting of 380 mJ, and if unsuccessful, a second attempt was made with an energy setting of 500 mJ. Three subjects required that a third and final attempt be made on the smallest finger of the nondominant hand. Subjects in study 2 returned for visual confirmation of wound healing 48 h after sampling.

Both studies were approved by the institutional review boards of the respective hospitals, and all subjects gave written informed consent before enrollment. Data from five subjects were excluded from analysis in study 1 secondary to the presence of chronic anemia (three subjects) or voluntary withdrawal from the study (two subjects). Data from one subject were excluded from analysis in study 2 because of failure to return for a wound check. Study 1 included 40 men and 55 women with a mean age of 50.4 ± 13.5 years, and study 2 included 44 men and 55 women with a mean age of 54.7 ± 13.8 years.