

Screening for Gestational Diabetes Mellitus

Use and Accuracy of Capillary Blood Glucose Measured With a Reflectance Meter

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Screening for gestational diabetes mellitus by a 1-hour glucose challenge test is recommended for all pregnant women between 24 and 28 weeks of pregnancy. Measurement of capillary blood glucose with a reflectance meter is well known and considered to be accurate, reliable, less costly, and more convenient than the laboratory test of plasma glucose. One hundred eighty-one pregnant women were tested with both a 1-hour glucose challenge test by capillary blood glucose and a 3-hour glucose tolerance test by venous plasma glucose. The diagnosis of gestational diabetes mellitus was made by the standard criteria on the 3-hour glucose tolerance test. The receiver operating characteristic curve was used to determine the optimum threshold value. There were seven cases of gestational diabetes mellitus detected during this study period, producing an incidence of 3.9%. The threshold value for the 1-hour glucose challenge test by capillary blood glucose was 9.0 mmol/L (163 mg/dL); the test has a sensitivity, specificity, predictive value, and likelihood ratio of 0.857, 0.868, 0.207, and 6.48, respectively. This test was at least as accurate as a 1-hour glucose challenge test by venous plasma glucose. Given its advantages, such as lower cost, simplicity, better patient acceptance, and immediate availability of the result, capillary blood glucose testing should be considered for screening of gestational diabetes mellitus in the office setting.

Gestational diabetes mellitus is an important, treatable cause of perinatal morbidity and mortality^{1,2} as well as a major risk factor for eventual maternal development of diabetes mellitus.^{3,4} In 1985 the Second International Workshop-Conference on Gestational Diabetes Mellitus and the US Centers for Disease Control recommended that all pregnant women be screened between the 24th and 28th week of pregnancy with a 1-hour glucose challenge test and that those with abnormal test results should undergo a diagnostic 3-hour glucose tolerance test. They also suggested that all glucose measurements be done on venous samples.^{5,6}

Even though high accuracy and reliability of capillary

blood glucose measured with a reflectance meter have been reported, especially when the measurements are performed by trained health personnel,⁷⁻⁹ the use of this method was not popular at the time of the recommendations. Capillary blood glucose testing also has the advantages of simplicity, lower cost, better patient acceptance, and immediate availability of the result.

This study examines whether capillary blood glucose testing can be used for the 1-hour glucose challenge test in place of venous plasma glucose with sufficient accuracy, and if so, what the appropriate threshold value is.

METHODS

From July 1, 1986, to December 31, 1987, 220 consecutive patients receiving their prenatal care in a university-based family practice residency were offered a 1-hour glucose challenge test by capillary blood glucose measured with a reflectance meter. If the result was equal to or more than

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TABLE 1. SUMMARY OF PATIENTS (N = 181)

Patient Characteristics	Number
Mean age in years (range)	24.9 (13-41)
Mean gestational age at 1-hour glucose challenge test (weeks)	26.7
Mean gestational age at 3-hour glucose tolerance test (weeks)	27.9
Incidence of gestational diabetes (%)	7/181 (3.9)

6.6 mmol/L (119 mg/dL), a 3-hour glucose tolerance test by venous plasma glucose was arranged within a week. The 3-hour glucose tolerance test for patients whose 1-hour glucose challenge test result was under 6.6 mmol/L was assumed to be normal. No patient had clinical evidence or a personal history of overt diabetes.

The capillary blood glucose measurements were performed by trained office nursing personnel 1 hour after intake of 50 g of glucose, regardless of the time of last meal or the time of day. Office personnel were trained to perform a fingerstick and to use reflectance meters according to the manufacturer's guidelines. Calibration of the equipment was performed at regular intervals using standards supplied with the test strips. The standard 3-hour glucose tolerance test was performed with intake of 100 g of glucose in the morning, after an overnight fast of at least 8 but not more than 14 hours, and after at least 3 days of unrestricted diet (≥ 150 g of carbohydrate) and physical activity. Venous samples were collected in tubes containing sodium fluoride and refrigerated at 4 °C until transported to the outside laboratory later that day. This national reference laboratory uses the glucose oxidase method in an automated spectrophotometer.

The criteria of the 3-hour glucose tolerance test for diagnosis of gestational diabetes mellitus adopted by the Second International Workshop-Conference on Gestational Diabetes Mellitus and Centers for Disease Control were used for this study. Accordingly, two or more of the following venous plasma glucose concentrations should be met:

- fasting ≥ 5.8 mmol/L (105 mg/dL)
- 1 hour ≥ 10.5 mmol/L (190 mg/dL)
- 2 hour ≥ 9.2 mmol/L (165 mg/dL)
- 3 hour ≥ 8.1 mmol/L (145 mg/dL)

The receiver operating characteristic curve of a diagnostic test is a graph of the pairs of sensitivity and 1 minus specificity that correspond to each possible cutoff for the diagnostic test result.¹⁰ This curve was used to determine the threshold value of the 1-hour capillary blood glucose challenge test.

RESULTS

Thirty-nine patients (17.7%) who did not complete either the 1-hour glucose challenge test or the 3-hour glucose tolerance test when indicated were excluded from the analysis. These excluded patients, however, were not different from the remaining 181 study patients with respect to age ($P = .48$). Table 1 is a summary of the study patient characteristics. The mean age of the study patients was 24.9 years with a range of 13 to 41 years. Among 181 study patients, 143 patients (79%) were screened between 24 and 32 weeks of pregnancy. Twenty-seven patients (15%) had their 1-hour glucose challenge test before 24 weeks of pregnancy, and 11 patients (6%) after 32 weeks. There were seven cases of gestational diabetes mellitus detected during this study period, producing an incidence of 3.9%.

Figure 1 shows the receiver operating characteristic curve. Use of this curve allows determination of the optimal threshold value for providing the best tradeoff between sensitivity and specificity. The point on this curve that is closest to the upper left-hand corner (sensitivity = 1, specificity = 1) is the best cutoff. This threshold value is marked with the arrow, and for this sample it was 9.0 mmol/L (163 mg/dL).

The accuracy of the 1-hour glucose challenge test by capillary blood glucose measured with a reflectance meter is shown in Table 2. Data from O'Sullivan et al¹¹ were included for comparison. The capillary blood glucose test showed better performance, especially in sensitivity, even though the significance of this finding could not be tested because the report by O'Sullivan et al did not include the data needed for a receiver operating characteristic curve. The likelihood ratio is defined as sensitivity/(1-specificity) and expresses the odds that a given level of a diagnostic test result would be expected in a patient with (as opposed to without) the target disorder. Because this ratio is very stable with changes in prevalence, many advocate this ratio in preference to the predictive value.¹² Even though the predictive value of this study appeared to be better, it might reflect only a difference in prevalence (3.9% vs 2.5%). The likelihood ratios were comparable.

DISCUSSION

The 1-hour glucose challenge test by capillary blood glucose with a threshold value of 9.0 mmol/L (163 mg/dL) was at least as accurate as the 1-hour glucose challenge test by venous plasma glucose. This result is also supported by two recently published studies that found capillary blood glucose threshold values of 8.3 mmol/L (150 mg/dL) and 8.8 mmol/L (160 mg/dL), respectively, in their study

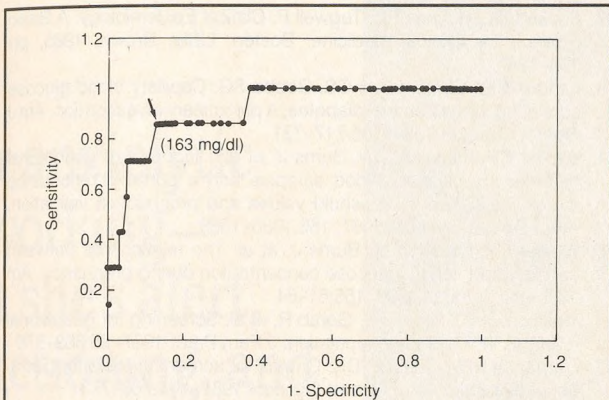


Figure 1. Receiver operating characteristic curve for 1-hour glucose challenge test of capillary blood glucose with indicated threshold of 9.0 mmol/L (163 mg/dL)

TABLE 2. ACCURACY OF THE 1-HOUR GLUCOSE CHALLENGE TEST BY CAPILLARY BLOOD GLUCOSE COMPARED WITH VENOUS PLASMA GLUCOSE

	Capillary Glucose	Venous Glucose*
Sensitivity	0.857	0.789
Specificity	0.868	0.872
Predictive value	0.207	0.138
Likelihood ratio	6.48	6.16

*Derived from O'Sullivan et al, 1973¹¹

populations.^{13,14} The differences in the threshold values seem to result from differences in methodology and criteria. Neither of these studies directly compared the 1-hour glucose challenge test by capillary blood glucose with the 3-hour glucose tolerance test so that the accuracy of the 1-hour test could be determined, as was done in this study.

It was assumed that a 3-hour glucose tolerance test in someone with a 1-hour glucose challenge test by capillary blood glucose under 6.6 mmol/L (119 mg/dL) would be normal. This assumption is justified for the following reasons. First, capillary blood glucose measured with a reflectance meter is known to be higher than the simultaneous venous plasma glucose in the postprandial state. The mean differences range from 0.9 to 2.0 mmol/L (16 to 32 mg/dL) 1 hour after a glucose load, depending on the size of glucose load.¹⁵ Second, the lowest cutoff value for the 1-hour glucose challenge test by venous plasma glucose ever reported was 7.2 mmol/L (130 mg/dL), under which value the authors assumed a 3-hour glucose tolerance test would be normal.^{16,17} As 7.2 mmol/L by venous plasma glucose is equivalent to 8.1 mmol/L (146 mg/dL) or more in capillary blood glucose, the study cutoff of 6.6 mmol/L allows a wide margin of safety in preventing false-negative results while avoiding some unnecessary 3-hour glucose tolerance tests. Indeed, in this study there was no positive 3-hour glucose tolerance test following a 1-hour glucose challenge test by capillary blood glucose value less than 7.8 mmol/L (140 mg/dL).

There are several limitations in this study. First, because the study sample size was relatively small, and only seven cases of gestational diabetes mellitus were detected, the receiver operating characteristic curve resulted in a step-like rather than a smooth curve. This small sample size

could affect the determination of the threshold value and its accuracy within a small range. Second, this study did not address user variability and quality control in performing the capillary blood glucose measurements. Standard office procedures were maintained in the performance of the capillary blood glucose measurements including standardization with each batch of new test strips. Subscribing to an outside service for external checks could increase quality control, but this step was not implemented in this study. Nevertheless, previous studies by others have documented the accuracy of capillary blood glucose testing compared with simultaneous venous blood glucose testing, indicating correlations of at least 0.90 when a reflectance meter is used.^{7,18} Third, the pregnant women in this sample were from a heterogeneous urban population. Sixty-three percent of the practice population were black and 36% were indigent (annual household income < \$10,000). Care needs to be taken before extrapolating from these results to a different kind of obstetric population.

Despite these limitations, the accuracy of capillary blood glucose testing to screen for gestational diabetes mellitus was well demonstrated in this study. Given the advantages of simplicity, lower cost, better patient acceptance, and immediate availability of result, consideration should be given to capillary blood glucose testing to screen for gestational diabetes mellitus, especially in the office setting. Further studies using a larger sample size would be useful for confirming these findings.

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