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The utility of a single glucometer measurement of fasting capillary blood glucose in the prevalence determination of diabetes mellitus in an urban adult Palestinian population

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This paper aims to evaluate the utility of a single glucometer fasting capillary blood glucose (FCBG) measurement in determining the prevalence of diabetes mellitus in a homogeneous adult population. FCBG measurements were compared with results of the oral glucose tolerance test (OGTT) in 445 subjects aged 30 – 65 years in an urban cross-sectional study in Old Ramallah. Prevalence of diabetes, sensitivity, specificity and predictive values were calculated at different cut-off levels of FCBG, using OGTT as the reference. The prevalence of OGTT-diagnosed diabetes was 2.7%, while it varied considerably using different cut-off levels of FCBG. The sensitivity of a single glucometer (Exac Tech II) measurement of FCBG at the cut-off level of 6.7 mmol l^{-1} was 33.3%, with a specificity of 98.8%. Using the cut-off level of 6.1 mmol l^{-1} as suggested by the 1998 provisional report of a WHO consultation, the sensitivity increased to 41.7%. At a cut-off level of 5.6 mmol l^{-1}, a sensitivity of 66.6% was reached, but the specificity decreased slightly. It can be concluded that a single glucometer measurement of FCBG in an adult population is not useful in determining the prevalence of diabetes mellitus.

Key words: Diabetes mellitus; FCBG; glucometer; prevalence; sensitivity; specificity; predictive values

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INTRODUCTION

Diabetes mellitus and its complications present a growing international public health concern, and in many countries it is considered an important cause of mortality, morbidity, disability and high healthcare cost [1]. Rapid demographic and socioeconomic changes in the Eastern Mediterranean region have led to alterations in the epidemiological patterns of diseases manifested by a declining incidence of infections and an increase in mortality and morbidity from non-communicable diseases [2]. This epidemiological transition should be examined carefully and monitored continuously using various indicators, including the prevalence of major non-communicable diseases such as Type 2 diabetes mellitus. Population-based data on the prevalence of diabetes in the Palestine Authority areas have only recently become available in rural and urban populations [3, 4]. The importance of determining the prevalence of diabetes and impaired glucose tolerance (IGT) cannot be over-emphasized. It has implications for healthcare needs assessment, identification of high-risk populations, estimation of future health services utilization and studying the etiology and risk factors associated with the disease [5].

Various tests have been suggested for identifying people with diabetes in the population, such as the oral glucose tolerance test (OGTT), glycated hemoglobin (GHb), fasting blood glucose (FBG), random blood glucose (RBG), fasting glycosuria and random glycosuria [5–13]. The World Health Organisation (WHO) recommends the use of OGTT, and has put forth diagnostic criteria for classification of subjects who undergo this test [1]. However, the OGTT is often considered cumbersome, time-consuming and patient-unfriendly [10]. Recently, new criteria emphasizing the use of fasting blood glucose (FBG) were suggested in a WHO consultation report [14].

The use of reflectance meters for glucose assessment has been evaluated in several studies [15, 16]. The objective of the present study is to evaluate the use of a single measurement of FCBG using a glucometer (Exac Tech II) in the prevalence estimation of type 2 diabetes using the OGTT as the reference (golden standard) in an adult population.

The issue of using a single determination of OGTT for epidemiological studies and population screening was noted in WHO guidelines [1] and considered more reliable than fasting values. For epidemiological or population screening purposes, the guidelines stated that "the 2-h value after 75 g oral glucose may be used alone or with the fasting value. The fasting value alone is considered less reliable since true fasting cannot be assured and spurious diagnosis of diabetes may more readily occur" [1].

SUBJECTS AND METHODS

Study design and population

A cross-sectional population-based study targeting males and females aged 30–65 years took place in April and May 1998 in the old part of Ramallah City [4]. Of a total eligible population of 831, all were invited, and 492 participated (59.2%). Of those that participated, 47 were excluded from analysis for the following reasons: previous diagnosis with diabetes (42), refusal to perform FCBG (1), absence of an OGTT measurement due to very high FCBG results (3), and an unrecorded FCBG result (1). Both 2 h OGTT and FCBG were performed on a total of 445 individuals.

Laboratory methods and statistical analysis

FCBG was performed immediately before the glucose load using a finger prick whole blood sample measured by the glucometer, which was calibrated daily in the morning and when starting a new batch of strips.

OGTT was performed according to the WHO recommended method (Table I) with a glucose load of 75 g in 250 ml of water preceded by an overnight fast of approximately 12 h [10–16], following at least 3 days of unrestricted diet [17].

Venous blood was drawn using the Becton and Dickinson vacutainer system 2 h after the glucose load and collected in sodium fluoride tubes. Following mixing and immediate centrifugation, plasma was separated and stored in an appropriate ice box, then transported to a nearby clinical laboratory where glucose determination was performed using a fully auto-

TABLE I. WHO recommended criteria for the diagnosis of diabetes mellitus [1, 2].

Diagnostic criteria	Diabetes mellitus mmol l^{-1}
OGTT (venous blood)	≥ 11.1
FBG new (capillary blood)	≥ 6.1
FBG old WHO (capillary blood)	≥ 6.7

mated clinical chemistry analyzer (Kone Supra Specific) utilizing the glucose oxidase method.

The laboratory applied internal and external quality control (QC) measures. In addition, duplicate samples were collected daily from a randomly selected participant, stored at −70°C and sent at the end of the survey to a referral laboratory (National Hospital, Rikshospitalet, Oslo, Norway). For additional quality control, a control sample was added daily to the patient samples by the investigators.

Both fasting venous plasma and fasting capillary blood glucose (FCBG) from finger prick were measured simultaneously for 30 randomly selected participants. Fasting venous plasma glucose was measured in the clinical laboratory using a fully automated clinical chemistry analyzer, while FCBG was measured in the study site using the (Exac Tech II) glucometer. Similarly, 30 randomly selected samples of 2-h OGTT blood were tested by both methods.

Statistical analysis was performed using the statistical program package SPSSWIN (Release 8.0). Calculations for sensitivity and specificity and predictive values (Table II) were performed according to Altman [18].

RESULTS

Characteristics of the non-responders

The mean ages of male and female non-responders were not significantly different from the respective responders. Sixty-one percent of the non-respondents were males who cited preoccupation with work as the reason for not responding in most cases. The response rates were similar in six out of eight residence blocks. However, the response rate was lower in one residence block inhabited by higher income families. Details of the study population have been described in a previous report [4].

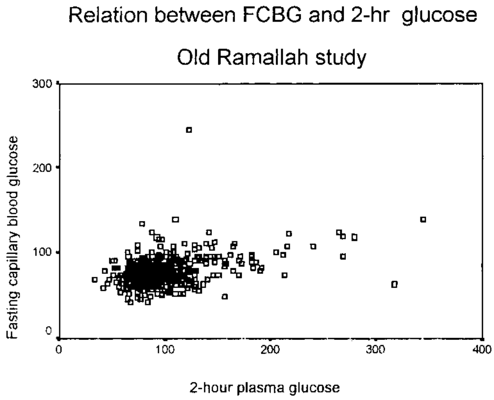

FIG. 1. The correlation between fasting capillary blood glucose (FCBG) and venous 2-h glucose (OGTT) for the participants in the Old Ramallah study.

FCBG and 2-h glucose

For the total sample the mean and the standard deviation for FCBG values was 4.4 ± 0.96 mmol l^{-1}, while for the 2-h glucose samples it was 5.5 ± 2.1 mmol l^{-1}. The correlation between FCBG values and the 2-h glucose values was $r = 0.38$, $p < 0.001$. The coefficients of variation (CV) were 21.8% and 38.2% for FCBG and the 2-h venous glucose, respectively. Fig. 1 shows the relation between fasting capillary blood glucose and venous 2-h glucose (OGTT).

The correlation between fasting capillary and venous blood glucose for the 30 duplicate samples was low ($r = 0.34$; $p \leq 0.05$). When the same protocol was applied to 2-h capillary

TABLE II. Test characteristics used to evaluate the FCBG.

Test characteristics were defined as follows:	Subjects with OGTT (+)	Subjects with OGTT (−)	Total
FCBG (+)	True (+) "A"	False (+) "B"	(A+B)
FCBG (−)	False (−) "C"	True (−) "D"	(C+D)
Total	(A+C)	(B+D)	(A+B+C+D)

Sensitivity = A/A + C
Specificity = D/B + D
Predictive value (+) = A/A + B
Predictive value (−) = D/C + D

glucose and 2-h venous glucose, the correlation coefficient doubled ($r = 0.73$; $p < 0.001$).

Sensitivity and specificity

Sensitivity increased with decreasing cut-off values of FCBG from 33.3% at 6.7 mmol l^{-1} to 83.3% at 5.0 mmol l^{-1} (Table III). Specificity stayed above 94% at all cut-off points except at 5.0 mmol l^{-1}, where it dropped to 79.0%. The positive predictive value was low for all cut-off values.

At the cut-off value of 5.0 mmol l^{-1} FCBG was able to identify 83.3% of those people classified as diabetic patients by OGTT. However, this increased sensitivity was at the expense of reduced specificity, meaning that the number of false-positive cases increased.

Fig. 2 shows the distribution of FCBG results in individuals classified by the OGTT as having diabetes and those not classified as diabetic individuals. At the cut-off point of 5.0 mmol l^{-1}, 10 out of 12 individuals classified as diabetes patients by OGTT had the same classification by FCBG, and, as expected, the number of individuals classified by both methods with diabetes decreased as the FCBG cut-off points increased.

Prevalence of diabetes detected by FCBG

Depending on the FCBG cut-off value chosen, the prevalence of diabetes varied between 2.0% and 22.7% (Table III). An FCBG cut-off value of 5.0 mmol l^{-1} gave the highest combined sensitivity and specificity. However, this cut-off point is not valid because it wrongly labels people as having diabetes when they are not considered so by the golden standard (OGTT).

At a cut-off value of 6.7 mmol l^{-1}, the FCBG determined prevalence of diabetes was 2.0%, and it was closest to the OGTT determined prevalence of 2.7%. It is important to note that, while the prevalence rates of 2.0% and 2.7% are close, they do not necessarily identify the same people.

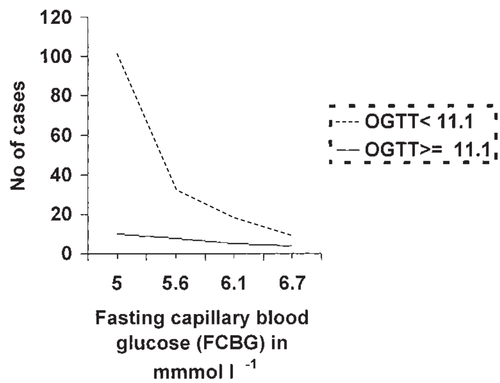

FIG. 2. The distribution of fasting capillary blood glucose (FCBG) results in individuals with and without diabetes according to 2-h oral glucose tolerance test (OGTT).

To obtain the same prevalence rate of 2.7% that was obtained by OGTT, the cut-off values for FCBG would have to be 6.5 mmol l^1. It should be noted here that the OGTT obtained prevalence is based on the results of the responders who composed 59.2% of those invited to participate in the study. The previously diagnosed persons with diabetes were not included in this figure. All the prevalence figures for the different cut-off values in Table III are those obtained when FCBG was used for diagnosis or classification, and the predictive values are calculated on this basis.

DISCUSSION

Determining the diabetes status of people using effective and valid methods is important for

TABLE III. Prevalence of diabetes at various cut-off points for fasting capillary blood glucose (FCBG), and sensitivity and specificity obtained by comparing FCBG with oral glucose tolerance test (OGTT) in a population of Palestinian adults.

FCBG cut off mmol l^{-1}.	Prevalence %	Sensitivity %	Specificity %	Predictive value (+) %
6.7 mmol l^{-1}	2.0	33.3	98.8	44.4
6.1 mmol l^{-1}	4.0	41.7	97.0	27.8
5.6 mmol l^{-1}	7.4	66.6	94.2	24.2
5.0 mmol l^{-1}	22.7	83.3	79.0	9.9

*OGTT determined prevalence was 2.7%.

clinicians and health service providers in order to offer an appropriate level of care and to plan the provision of health services and resource allocation effectively. Different criteria for effective and appropriate diabetes screening have been put forth and evaluated [6, 7]. Screening is defined as "the use of a simple test to discriminate between people who are likely to have a disease and those who are likely not to have it" [7]. The functions and characteristics of confirmatory tests are different from those of screening tests, and therefore the criteria to judge their effectiveness are different.

In this survey, the response rate was lower in males than in females, in part, for work-related reasons. While many men work outside of the Old Ramallah area, most of the females participating in the study were housewives (79%). However, in a similar study performed in a rural community in the Ramallah district, the prevalences of previously diagnosed and survey diagnosed diabetes were not significantly different between males and females [3]. Almost equal distribution of diabetes prevalence between males and females was shown in data coming from other studies performed in the Eastern Mediterranean region [19]. Although there is no significant difference in the mean age between the responders and non-responders, the effect of the low response rates among elderly males may have caused an underestimation of the prevalence in that group [4]. However, this will not affect the sensitivity and specificity, but may affect the predictive values.

We detected a marked difference between the two correlation coefficients for fasting blood glucose and 2-h blood glucose measurements. On the one hand, the correlation coefficient for glucometer measured FCBG and venous FPG measured by the clinical chemistry analyser was $r = 0.34$. On the other, the correlation coefficient for glucometer measured 2-h blood glucose and 2-h venous plasma glucose measured by the clinical chemistry analyser was $r = 0.73$. This difference means that glucometers will yield better results when used in measuring 2-h capillary blood glucose than in measuring FCBG. A possible explanation for the difference could be that the results had lesser spread in the fasting glucose, while there was a better spread over a wider range of values in the 2-h glucose. The CV for the 2-h glucose is higher than that of FCBG, which supports the previous explanation since it indicates a larger variance and a better spread over a wider range.

The low correlation between capillary and venous fasting glucose could be explained partially by the use of whole blood in the FCBG and venous plasma in FPG; or because two different methods were used in the determination of glucose for the whole blood and the plasma.

Based on the sum of sensitivity and specificity, 5.0 mmol l^{-1} was calculated to be the best cut-off value. This is not necessarily the most appropriate cut-off value because it is based only on sensitivity and specificity. Giving equal weight to sensitivity and specificity and not taking prevalence and predictive values into consideration can pose a problem for interpretation. Weights should also be given to false-positive and false-negative rates. However, these weights cannot be determined on the basis of a single study and must be the subject of further discussion.

Sensitivity, specificity and predictive values results presented in Table III have shown reduced ability of FCBG measured by hand-held glucometers for the diagnosis of diabetes and categorizing people into diabetic patients and non-diabetic individuals.

A recent paper in which 20 different European studies were reviewed concluded that if fasting glucose is used alone to determine diabetes status, 31% of patients with a diabetic 2-h glucose (OGTT) result would not be identified [20].

The closest prevalence to the golden standard (OGTT) determined prevalence was achieved with an FCBG cut-off value of 6.7 mmol l^{-1}. However, the sensitivity at this cut-off point was fairly low (33.3%), indicating that 66.7% of people with a diabetic 2-h glucose (OGTT) result would not be classified as diabetes patients by FCBG. We conclude that the use of FCBG measured using a glucometer (Exac Tech II) is not a viable alternative for OGTT for the time being. This is in accordance with a previous study on the use of fasting blood glucose in determining the prevalence of diabetes in a homogeneous population of Caucasian middle-aged women [5].

The need for a simple, cost-effective and scientifically valid diagnostic test for diabetes is indisputable. This need is even more pressing in developing-country settings, where OGTT is costly and difficult to perform due to the unavailability of resources. As a result, a large number of cases may go undetected, causing a human and economic burden in the form of cases which would never have reached the level of advanced complications if detected earlier. Blood glucose determination may be used for the purpose of case-finding (clinical diagnosis), where it has to be highly sensitive and specific to pick the individuals with diabetes, as well as for descriptive epidemiological studies where more emphasis is put on the test's ability to determine the prevalence correctly. Development of a test with the above-mentioned characteristics for both purposes and for use in analytical epidemiological studies is the ultimate aim. However, even a test which can be used for descriptive epidemiological investigations would be highly beneficial, at least to inform appropriate health planning and resources allocation. One option that should be further explored in other studies is the ability to calculate a ratio between OGTT (old criteria) or FPG (new criteria) classified diabetes and FCBG classified diabetes, which would enable us to estimate the prevalence of diabetes using the glucometer glucose determination.

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