

## THE PERFORMANCE OF THE REVISED CRITERION FOR DIAGNOSIS OF DIABETES MELLITUS IN JORDAN

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Diabetes mellitus (DM) is a major health problem worldwide. The World Health Organization (WHO) criteria for the diagnosis of DM—fasting plasma glucose (FPG)  $\geq 7.8$  mmol/L, and/or plasma glucose (PG)  $\geq 11.1$  mmol/L two hours after a 75 g oral glucose load (2-h PG)<sup>1</sup>—were useful in unifying the definition of the disease, and thus enhancing comparability of the data from different countries. The Expert Committee on the Diagnosis and Classification of Diabetes of the American Diabetes Association (ADA) has recently recommended the use of FPG  $\geq 7$  mmol/L for the diagnosis of DM.<sup>2</sup> This new criterion simplifies the diagnosis of DM and reduces the cost and inconveniences associated with the oral glucose tolerance test (OGTT). The usefulness of this new criterion have been assessed in some populations,<sup>3-6</sup> but the conclusions were variable. In the present study, we assess the validity of this new criterion in Jordan separately, against the current WHO criteria and against the 2-h PG alone. To our knowledge, there have been no previous reports on this topic from Arab or Middle Eastern countries.

### Subjects and Methods

A community-based survey was conducted in four Jordanian towns between September 1994 and February 1996. Details of the survey have been published elsewhere.<sup>7</sup> In brief, a total of 2836 subjects who were  $\geq 25$  years of age were assessed for cardiovascular risk factors, including diabetes, hypertension, hyperlipidemia, obesity, and smoking. The overall response rate in that survey was 70.5%. Selected households were visited at home and residents were invited to report to the local health center on a given date after an overnight fast. In the health center, we obtained two blood samples from each participant, each of whom had been fasting, and two hours after a 75-g oral glucose load. Laboratory tests were carried out on the same day of blood collection, using standard laboratory techniques.

The Statistical Analysis System (SAS) software was used for data cleaning, recording, and statistical analysis. Epi 6

software was used to calculate the observed agreement and the agreement beyond chance (Kappa statistic).<sup>8</sup> For the purpose of this report, patients known to be diabetic were excluded. Missing or implausible data on a variable were deleted from analysis of that particular variable, which resulted in some minor inconsistencies of the totals.

Sensitivity, specificity, observed agreement, and the agreement beyond chance were obtained for the new criterion (FPG  $\geq 7$  mmol/L) against the WHO definition of DM, and also against the 2-h PG. The significance of the Kappa statistic was given as a one-tailed *P*-value, as recommended.<sup>8</sup> Similar parameters were estimated for FPG  $\geq 7.8$  mmol/L against the 2-h PG.

### Results

Our results were based on a sample of 2836 subjects, of whom 63% were women. Their ages ranged from 25 to 88 years, with a mean of 44.3 years (SD 14.2). Previously diagnosed diabetic patients were excluded.

The sensitivity, specificity, observed agreement, and agreement beyond chance of the new criterion (FPG  $\geq 7$  mmol/L) against the WHO definition of diabetes, and against the 2-h PG are shown in Tables 1 and 2, respectively. Taking the WHO definition of diabetes as a gold standard, the new criterion was able to correctly classify 88% of the cases (sensitivity) and 98% of the noncases (specificity). The two tests agreed in 97% of the study population, although agreement beyond that expected by chance was 73% ( $P < 0.0001$ ) (Table 1).

When the new criterion was compared with the 2-h PG  $\geq 11.1$  mmol/L, the sensitivity and specificity were 78% and 96%, respectively, while the observed agreement and agreement beyond chance were 96% and 50%, respectively (Table 2). However, the sensitivity was lower (69%) when the old criterion (FPG  $\geq 7.8$  mmol/L) was compared to the 2-h PG test (Table 3). The predictive value of a positive test (FPG  $\geq 7$  mmol/L), however, was rather low (65% and 39%), in reference to the WHO and 2-h PG, respectively.

Based on the WHO definition, the prevalence of previously undiagnosed DM was 5.1%, compared to 6.8% using the new criterion. The data were also examined for agreement between impaired fasting glucose (IFG) (FPG 6.1-6.9 mmol/L) and IGT (2-h PG 7.8-11 mmol/L). Only 29.6% of subjects with IGT had IFG. Conversely, 20.1% of subjects with IFG had IGT.

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TABLE 1. Fasting plasma glucose (FPG) 7 mmol/L against the WHO definition of diabetes.

FPG	WHO definition*		Sen	Sp	Ag	Kappa
	DM	No DM				
≥ 7 mmol/L	112	59	88%	98%	97%	73%
< 7 mmol/L	16	2326				

WHO definition of DM=FPG ≥7.8 mmol/L and/or plasma glucose ≥11.1 mmol/L 2 hours after a 75 g oral glucose load; Sen=sensitivity of FPG; Sp=specificity of FPG; Ag=observed agreement; Kappa=Kappa statistic which measures agreement beyond chance.

TABLE 2. Fasting plasma glucose 7 mmol/L against 2-h PG level.

FPG	2-h plasma glucose (mmol/L)		Sen	Sp	Ag	Kappa
	≥11.1	<11.1				
≥ 7 mmol/L	58	91	78%	96%	96%	50%
< 7 mmol/L	16	2417				

TABLE 3. Fasting plasma glucose 7.8 mmol/L against 2-h PG level.

FPG	2-h plasma glucose (mmol/L)		Sen	Sp	Ag	Kappa
	≥11.1	<11.1				
≥ 7.8 mmol/L	51	32	69%	99%	98%	64%
< 7.8 mmol/L	23	2385				

## Discussion

As with most measurements on a continuous scale, the selection of a cutoff point to differentiate between the sick and the well is frequently problematic. Such cutoff points have to be periodically revised and changed when appropriate, based on the accumulation of new knowledge. The ADA recommendation for lowering the FPG cutoff point from 7.8 to 7 mmol/L is consistent with the findings of a number of studies regarding the risk of diabetes at lower FPG values.<sup>9-11</sup> Previous studies assessed the usefulness of the ADA recommendation in different populations.<sup>3-6</sup> Some of these studies recommended the use of the new criterion,<sup>4,5</sup> while a study from several European countries<sup>3</sup> and another from the UK<sup>6</sup> found that the new criterion was associated with an appreciable degree of misclassification of the diabetic status. A study among high-risk Hong Kong Chinese women advocated the use of FPG together with HbA<sub>1c</sub> or fructosamine.<sup>12</sup> The dilemma has been highlighted by Goldstein in a recent article.<sup>13</sup>

Our data suggest that the new criterion may be useful for screening purposes. Besides its simplicity, misclassification occurs only in 3% of the population. However, subjects who test positive should undergo further testing, as a large proportion are false-positives (35% and 61% in reference to WHO and 2-h FPG, respectively). These later rates, of course, depend on the prevalence of undiagnosed DM in the population, and will decrease as the prevalence increases. Limiting the use of OGTT to subjects who test positive (FPG ≥7 mmol/L) is more feasible, less costly, and avoids the associated inconveniences. As regards the prevalence of undiagnosed DM, the new criterion was associated with a

higher prevalence (6.8%) compared to the WHO criteria (5.1%), a finding in agreement with data from several European countries<sup>3</sup> and from the UK.<sup>6</sup> It should be noted that the agreement between the categories of IFG and IGT was poor.

In conclusion, our data suggest that FPG ≥7 mmol/L may perform well in epidemiological studies, especially when the prevalence of undiagnosed DM is high, and that further testing of detected cases is necessary to identify false positives. Further studies are needed to characterize precisely the risk of diabetes complications at different FPG and 2-h PG levels.

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