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Articles

Is fasting glucose sufficient to define diabetes? Epidemiological data from 20 European studies

The DECODE-study group on behalf of the European Diabetes Epidemiology Group*

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Abstract

Aims/hypothesis. The World Health Organisation Consultation recommended new diagnostic criteria for diabetes mellitus including: lowering of the diagnostic fasting plasma glucose to 7.0 mmol/l and introduction of a new category: impaired fasting glycaemia. The diagnostic 2-h glucose concentrations for diabetes and for impaired glucose tolerance were unchanged. This study identifies fasting plasma glucose concentrations predicting a diabetic 2-h plasma glucose of 11.1 mmol/l or more, analyses the sensitivity and specificity of different screening strategies for diabetes and describes the cardiovascular risk profile in people with impaired fasting glycaemia.
Methods. European population based studies ($n = 17$) or large, representative samples of employees ($n = 3$) with both fasting and 2-h post load glucose concentrations following 75-g oral glucose tolerance tests were included (18 918 men and 10 190 women). The Iceland study (8881 men and 9407 women) is presented separately as a 50-g glucose load was used.
Results. The fasting plasma glucose predicting a 2-h plasma glucose of 11.1 mmol/l or more with optimal sensitivity and specificity was a) 5.8 mmol/l in women and 6.4 mmol/l in men; b) independent of age; c) increased with obesity. Fasting plasma glucose of 7.0/7.8 mmol/l or more predicted a diabetic 2-h plasma glucose with sensitivities of 49.0/29.8 % and specificities of 98.2/99.7 %, respectively.
Conclusion/interpretation. If fasting glucose is used alone, the 31 % of diabetic subjects with a non-diabetic fasting glucose but a diabetic 2-h glucose, will not be diagnosed; impaired fasting glycaemia and impaired glucose tolerance do not identify the same people; the risk profile of people with impaired fasting glycaemia depends on 2-h glucose concentrations. Obesity is the main confounder in the association between fasting and 2-h glucose. [Diabetologia (1999) 42: 647–654]

Keywords Diabetes, diagnosis, diagnostic criteria, epidemiology, ROC-analysis, risk factors.

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Abbreviations: FPG, fasting plasma glucose (mmol/l); 2hPG, plasma glucose (mmol/l) at 2 h following an OGTT; ADA, American Diabetes Association; WHO, World Health Organisation; ROC-curve analysis, Receiver Operator Characteristics Curve analysis (Graphical presentation of the sensitivity and specificity of variable X as predictor of outcome Y); IFG, impaired fasting glycaemia.
* see Acknowledgements

New diagnostic criteria for diabetes mellitus were approved by the American Diabetes Association (ADA) in 1997 [1] and in 1998 the World Health Organisation (WHO) Consultation published their provisional report [2]. The ADA Expert Committee and the WHO Consultation both recommend that for diagnosing diabetes, the cut-point for the fasting plasma glucose (FPG) should be lowered from 7.8 to 7.0 mmol/l but the concentration of 2-h plasma glucose (2hPG) following a 75-g oral glucose tolerance test (OGTT) should remain unchanged at 11.1 mmol/l.

There were several reasons for these recommendations. Two cross sectional [3, 4] and one prospec-

tive [5] study had shown that FPG in the interval 7.0 to 7.8 mmol/l was associated with an increased risk of microvascular retinal complications. One prospective study had shown that slightly elevated (but not diabetic) FPG values were associated with an increased mortality from coronary heart disease [6]. Several studies have shown that, at the time of clinical diagnosis of diabetes, the prevalence of microvascular and macrovascular complications may be as high as 30–40 % [7–10] and the estimated median diabetes duration at the time of clinical diagnosis is more than 5 years [11]. Thus, the ADA Expert Committee and the WHO Consultation both recommended a lowering of the FPG value to define diabetes and, according to the WHO Consultation, 7.0 mmol/l was chosen "to represent a value which in most persons is of approximately equal diagnostic significance to that of the 2-h post-load concentration". Furthermore, to simplify the diagnosis and to facilitate earlier diagnosis, the ADA recommended the use of the fasting value as the primary diagnostic tool. In contrast the WHO Consultation advised retaining the 2-h post load measurement.

Previously, we have shown that despite a relatively small change in the overall prevalence of diabetes using only the 2hPG compared with only the FPG, there was a considerable change in the classification of people [12]. The aim of the present paper is to: 1. Analyse whether a FPG value of 7.0 mmol/l has an "equal diagnostic significance" to the 2hPG of 11.1 mmol/l. 2. Evaluate the potential effect of different stepwise screening strategies for diabetes based on measurement of FPG followed by a 2hPG if a patient has fasting hyperglycaemia. 3. Compare the classification of people in the two groups: impaired glucose tolerance (IGT) and impaired fasting glucose (IFG) and to evaluate the cardiovascular risk profile in the IFG group according to the 2-h glucose category, as cardiovascular disease is the leading cause of death in people with Type II (non-insulin-dependent) diabetes mellitus and IGT.

Subjects and methods

All centres in Europe with studies on the prevalence of diabetes mellitus in adults, either population based studies or studies in large representative samples of occupational groups, were invited to participate. This article includes data on 47 396 subjects (27 799 men and 19 597 women) without previously diagnosed diabetes from 17 [13–29] population-based studies and 3 [30–32] in occupational groups. The design and data collection has been described in detail in a previous publication [12]; four new centres have been included in this analysis, from London, United Kingdom (the Goddinge Study) [26], Malta [27], Västerbotten, Sweden [28] and Iceland [29].

Each centre provided crude original data on their population including age, sex, date of examination, height, weight, status of known diabetes, glucose load (75 g for all except Iceland), fasting and 2-h post load glucose, blood specimen used, glucose assay and, where available, blood pressures (Korotkoff phase one and five), serum-cholesterol and smoking status (current, ex- or never smoker). Data from Iceland were analysed separately as they used a 50-g OGTT. Data were sent to the Diabetes and Genetic Epidemiology Unit of the National Public Health Institute in Helsinki, Finland. Data were analysed for each centre individually and then on a pooled basis (where possible).

When data were analysed by categories of glucose tolerance (normal, IFG, IGT, diabetes mellitus) all studies using a 75-g OGTT (all centres except Iceland) were included. The corresponding fasting values for glucose in plasma, serum, venous whole blood and capillary whole blood were: 6.1 = 6.1 = 5.6 = 5.6 mmol/l; 7.0 = 7.0 = 6.1 = 6.1 mmol/l and 7.8 = 7.8 = 6.7 = 6.7 mmol/l. For 2-h post load concentrations, the corresponding values were: 7.8 = 7.8 = 6.7 = 7.8 mmol/l; 11.1 = 11.1 = 10.0 = 11.1 mmol/l [2]. The analyses were based on individual glucose values given by the centres. As the centres had carried out their studies independently, there was no central laboratory nor central quality control of the glucose assays.

Chi-squared tests were used to test whether the classification according to fasting and 2-hour glucose concentrations was homogeneous between study centres, in sex-age specific strata.

For the receiver operator characteristics curve (ROC)-analyses, only centres measuring plasma glucose concentrations were included due to the lack of conversion factors between glucose concentrations in plasma, serum, venous whole blood and capillary whole blood ROC-analysis [33] was used to identify an optimal FPG concentration which maximised the sensitivity and specificity with respect to the 2hPG of 11.1 mmol/l. The sensitivity and specificity of a FPG of 7.0 and 7.8 mmol/l were also evaluated, as were the effects of sex, age and BMI.

The sensitivity and specificity of two stepwise screening strategies for diabetes and IGT in the population were evaluated; measurement of FPG in the entire population and an OGTT with a 2hPG only if the FPG was either more than 5.5 mmol/l or more than 6.0 mmol/l. These values were chosen as a random plasma glucose less than 5.5 mmol/l which is stated as "Diabetes mellitus unlikely" by the WHO Consultation [2], and FPG of 6.1 mmol/l or more is the lower limit for IFG [1, 2]. In both cases we estimated the percentage of the population needing an OGTT and the percentage of people with diabetes or IGT that would not be identified using the stepwise strategy.

The cardiovascular risk profile was studied in the IFG group, subdivided according to 2-h glucose concentrations. Characteristics were compared using analysis of covariance, adjusted for age.

Data were analysed at the National Public Health Institute in Helsinki, using SPSS version 7.5.1 for Windows.

Results

The study included 18 918 men [age, 53.1 years (± 11.1), means (± SD); BMI, 26.1 kg/m^2 (± 3.4)] and 10 190 women [age, 53.7 years (± 11.8); BMI, 26.2 kg/m^2 (± 4.9)] all receiving a 75-g OGTT. Furthermore, data from Iceland are presented separately as they used a 50-g OGTT [8881 men; age, 52.2 years (± 8.6), BMI, 25.7 kg/m^2 (± 3.4), and 9407 women; age: 53.7 years (± 11.8), BMI, 26.2 kg/m^2 (± 4.9)]. Data on age, BMI, and glucose concentrations (fast-

Table 1. Characteristics of subjects [mean (SD), or percentage] included in the DECODE Study, by sex (people with previously diagnosed diabetes are not included)

Population	No.	Age (years)	BMI (kg/m^2)	Blood pressure (mm Hg)		Cholesterol (mmol/l)	Smoker (%)	Glucose[c]
				Systolic	Diastolic			
Men								
POL-MONICA, Poland	172	58.1 (8.4)	26.5 (4.1)	136 (22)	82 (13)	5.5 (1.0)	46.8	Serum
Vantaa, Finland	244	71.7 (0.5)	26.8 (3.7)	–	–	–	–	VWB
Pieksämäkis, Finland	249	43.1 (5.7)	28.2 (3.6)	142 (18)	87 (12)	5.8 (1.1)	–	VWB
Oulu, Finland								
Middle-aged	328	55.0 (0)	26.6 (3.4)	150 (18)	94 (10)	5.7 (1.2)	29.2	CWB
Elderly	120	75.7 (4.9)	26.7 (3.5)	150 (24)	82 (11)	4.3 (0.4)	11.1	CWB
E&W men, Finland	354	76.0 (4.5)	26.3 (3.7)	156 (22)	85 (11)	5.7 (1.1)	14.1	PG
Newcastle, England	403	54.7 (12.7)	26.3 (3.9)	134 (22)	80 (12)	–	29.5	PG
Goodinge, England	454	54.7 (10.3)	25.5 (4.1)	121 (20)	72 (12)	6.3 (1.2)	41.2	PG
Zutphen, the Netherlands	445	75.7 (4.5)	25.6 (3.2)	150 (22)	82 (12)	6.1 (1.1)	22.6	PG
Cremona, Italy	735	56.7 (10.4)	26.6 (3.6)	145 (20)	81 (12)	6.0 (1.1)	32.5	PG
Malta	754	50.0 (13.1)	27.1 (4.3)	137 (20)	84 (11)	–	–	CWB
FIN-MONICA, Finland	893	54.6 (5.9)	27.8 (3.8)	144 (19)	88 (11)	6.0 (1.0)	26.5	PG
Glostrup, Denmark	1010	52.2 (12.0)	25.2 (3.4)	135 (22)	84 (12)	6.9 (1.3)	15.4	VWB
Västerbotten, Sweden	1035	49.7 (11.1)	26.0 (3.4)	131 (18)	84 (11)	6.3 (1.2)	18.6	PG
Hoorn, the Netherlands	1102	61.2 (7.3)	26.2 (2.9)	135 (19)	84 (10)	6.4 (1.1)	41.1	PG
Uppsala, Sweden	1111	71.0 (0.6)	26.2 (3.4)	147 (18)	84 (9)	–	15.9	PG
Helsinki police, Finland	1120	44.6 (8.0)	25.7 (2.8)	138 (18)	83 (11)	6.1 (1.2)	48.8	VWB
Telecom, France	1355	43.6 (9.9)	24.8 (3.0)	133 (16)	79 (12)	6.2 (1.1)	–	PG
Paris, France	7034	49.0 (2.0)	26.0 (3.3)	144 (22)	81 (13)	5.7 (1.1)	64.0	PG
Iceland[a]	8881	52.2 (8.6)	25.7 (3.4)	–	–	–	54.1	CWB
Overall[b]	18918	53.1 (11.1)	26.1 (3.4)	141 (21)	82 (12)	6.0 (1.2)	44.0	
Women								
POL-MONICA, Poland	187	57.7 (8.5)	29.3 (4.9)	138 (20)	81 (11)	5.9 (1.0)	6.4	Serum
Pieksämäkis, Finland	264	43.1 (5.9)	28.1 (5.7)	135 (19)	82 (10)	5.3 (1.0)	–	VWB
Vantaa, Finland	307	71.8 (0.4)	27.4 (4.6)	–	–	–	–	VWB
Newcastle, England	376	54.7 (12.3)	26.4 (5.0)	128 (24)	71 (11)	–	26.2	PG
Oulu, Finland								
Middle-aged	431	55.0 (0)	26.5 (4.3)	143 (18)	89 (10)	5.9 (1.3)	18.8	CWB
Elderly	189	76.3 (4.8)	28.8 (4.8)	162 (27)	81 (11)	4.2 (0.3)	3.3	CWB
Goodinge, England	585	54.6 (10.3)	25.9 (5.2)	118 (21)	68 (11)	6.6 (1.4)	35.6	PG
Cremona, Italy	937	58.8 (10.9)	26.1 (4.7)	142 (21)	78 (12)	6.3 (1.2)	14.9	PG
Glostrup, Denmark	964	50.5 (11.8)	24.1 (4.3)	130 (25)	79 (11)	6.8 (1.6)	43.5	VWB
Malta	991	48.2 (12.6)	29.1 (5.9)	138 (22)	86 (12)	–	–	CWB
FIN-MONICA, Finland	1070	54.5 (6.0)	27.1 (4.6)	140 (20)	83 (10)	6.0 (1.1)	14.5	PG
Västerbotten, Sweden	1094	49.3 (11.1)	25.6 (4.6)	129 (21)	80 (11)	6.3 (1.3)	24.4	PG
Hoorn, the Netherlands	1278	61.8 (7.4)	26.7 (3.9)	135 (21)	81 (11)	6.9 (1.2)	27.7	PG
Telecom, France	1517	46.0 (9.5)	23.4 (3.7)	123 (14)	72 (11)	6.0 (1.1)	–	PG
Iceland[a]	9407	52.8 (8.5)	25.0 (4.2)	–	–	6.3 (1.3)	40.5	CWB
Overall[b]	10190	53.7 (11.8)	26.2 (4.9)	133 (22)	79 (13)	6.4 (1.4)	24.5	

[a] 90-min glucose, 50-g glucose loading
[b] Not including Iceland
[c] PG = Plasma glucose, Serum = Serum glucose, VWB = Venous whole blood glucose, CWB = Capillary whole blood glucose

ing and 2-h) were available in all populations and data on BP, serum-cholesterol and smoking (current, ex- or never smoker) were available in the majority of studies (Table 1).

Association between fasting and 2-h plasma glucose values. The ROC-curves did not differ between the sexes (Fig. 1) but the optimal cut-point was higher in men than in women (6.4 vs 5.8 mmol/l, Table 2). Subdividing the group into four age strata (< 50 years, 50–64 years, 65–74 years and ≥ 75 years) we found no difference in the optimal FPG cut-point (range 6.0–6.3 mmol/l). In obese people (BMI ≥ 30 kg/m^2) the optimal FPG cut-point was 6.6 mmol/l, lower than the diagnostic value for diabetes of 7.0 mmol/l, with a sensitivity of 75 % and a specificity of 91 % (Table 2). In people of normal weight, the FPG cut-point decreased to 5.8 mmol/l and both sensitivity and specificity decreased greatly (Fig. 2). Men and women had similar mean BMI and the optimal cut-point decreased with decreasing BMI in both sexes (data not shown).

Among people with 2hPG 11.1 mmol/l or more (diabetic) more than 50 % had a FPG less than 7.0 mmol/l and 31 % had a normal FPG according to the revised criteria (Fig. 3). Thus, almost one in three people diabetic according to the 2hPG would be declared normal if only FPG was available. Among peo-

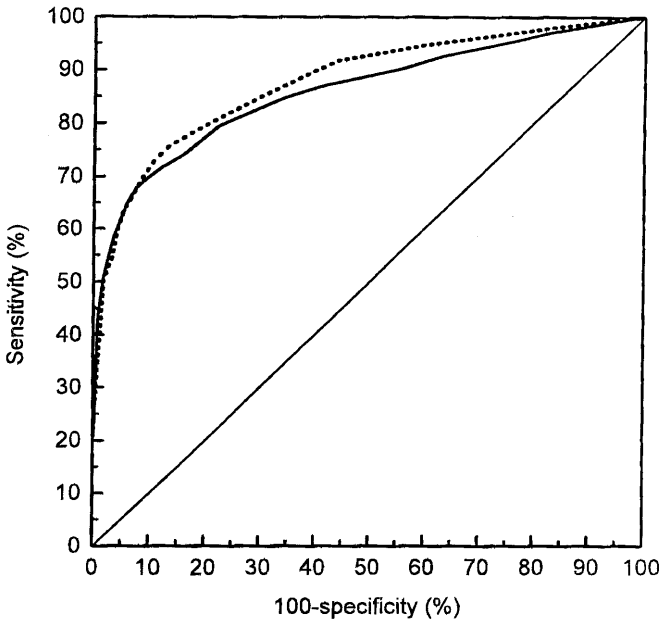

Fig. 1. Receiver Operator Characteristic (ROC) curves for fasting venous plasma glucose predicting a 2-h plasma glucose of 11.1 mmol/l or more in the 14 291 men (____) and the 6857 women (. . . . .). The DECODE Study

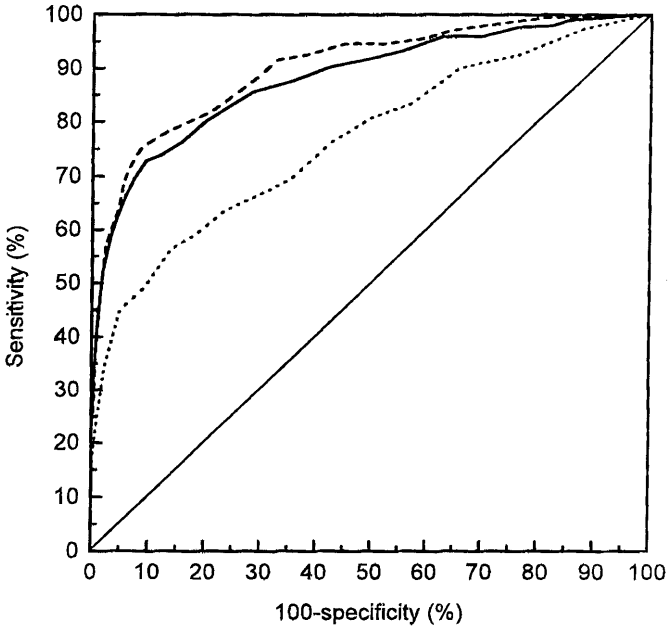

Fig. 2. Receiver Operator Characteristic (ROC) curves for fasting venous plasma glucose predicting a 2-h plasma glucose of 11.1 mmol/l or more in the 9334 lean (BMI < 25 kg/m^2) (. . . . .), 9507 overweight (BMI 25–29 kg/m^2) (____) and 2808 obese (BMI ≥ 30 kg/m^2) (– – –) people. The DECODE Study

Table 2. Optimal fasting plasma glucose (mmol/l) cut-points corresponding to a 2-h plasma glucose concentration 11.1 mmol/l or more, according to sex and BMI. People without previously diagnosed diabetes and with glucose from plasma samples. The DECODE Study

	No.	Fasting plasma glucose (mmol/l) cut-point	Sensitivity %	Specificity %
Sex				
Men	14921	6.4	67.8	92.5
Women	6857	5.8	75.7	86.6
Both	21778	6.2	69.6	90.0
BMI (kg/m^2)				
< 25	9334	5.8	56.3	86.1
25–29	9507	6.3	72.8	90.5
≥ 30	2808	6.6	75.4	91.1

ple with 2hPG in the IGT range, nearly 70 % had normal FPG whereas 23 % had FPG in the IFG range.

Among people with FPG in the IFG range, 7 % were diabetic on the 2-h value but 29 % had values in the IGT range (Fig. 4) and two thirds had a normal 2hPG. People who had a diabetic FPG based on the former criteria (≥ 7.8 mmol/l) or only according to the new diagnostic criteria (7.0–7.7 mmol/l) had normal 2hPG values in 7 % and 35 % of instances, respectively.

Fasting and 2-h post load plasma glucose concentrations and screening strategies. The percentage of subjects with previously undiagnosed diabetes (equivalent to FPG ≥ 7.0 mmol/l and/or 2hPG ≥ 11.1 mmol/l) was 5.7 %, and 11.9 % had IGT (equivalent to FPG < 7.0 mmol/l and 2-h glucose 7.8 to 11.0 mmol/l) (Table 3). This classification was not homogeneous between centres, in sex and age specific strata (all $p < 0.001$).

If a stepwise strategy used the 2hPG only in people with FPG more than 5.5 mmol/l and less than 7.0 mmol/l (the lower level for diabetes), 46 % of the population would need an OGTT. This strategy would identify 93 % of all people with diabetes based on 2hPG of 11.1 mmol/l or more and 69 % of all with IGT. If a stepwise strategy where an OGTT was used only if FPG was 6.1 to 6.9 mmol/l (the IFG group) only 12 % would need an OGTT but this strategy would only identify 82 % of people with diabetes and 29 % of those with IGT.

Comparison of impaired glucose tolerance with impaired fasting glucose. Among the 29 108 people without previously diagnosed diabetes, 3119 had IFG (Table 3). Among these, 65 % had normal 2-h glucose concentrations and 7 % had a diabetic 2-h glucose. Among the 3833 subjects with 2-h glucose in the IGT range, 67 % had normal fasting glucose, while 23 % had fasting values in the IFG range.

The distribution of cardiovascular risk factors in the IFG group depended on the 2-h glucose concentrations (Table 4). Systolic and diastolic blood pressure increased with increasing 2-h glucose for peo-

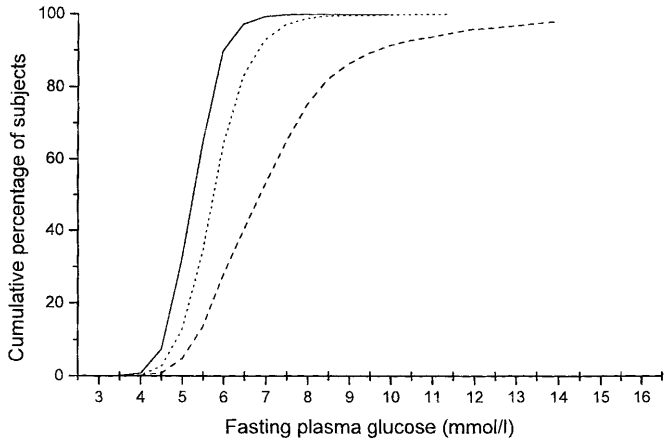

Fig. 3. Cumulative distribution of fasting plasma glucose for people with normal, less than 7.8 mmol/l, (_____), impaired glucose tolerance, 7.8–11.0 mmol/l, (. . . . . .) and diabetes, more than 11.1 mmol/l, (– – –) according to 2-h plasma glucose concentrations. The DECODE Study

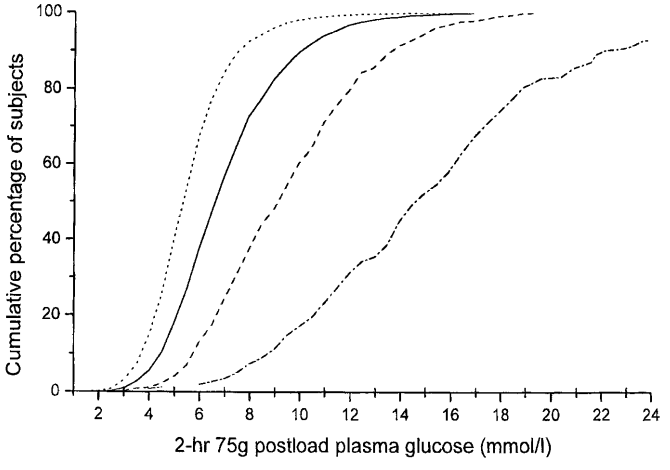

Fig. 4. Cumulative distribution of 2-h plasma glucose for people with normal, less than 6.1 mmol/l, (. . . . . .), impaired fasting glycaemia, 6.1–6.9 mmol/l, (_____), diabetes with FPG 7.0–7.7 mmol/l (– – –) or diabetes with FPG ≥ 7.8 mmol/l (– · – · – · –), according to fasting plasma glucose concentrations. The DECODE Study

ple with IFG, except in women aged 60 years and over. Body mass index increased with increasing 2-h glucose except in the older men and for serum-cholesterol, an effect was only seen in the older women.

Discussion

The main difference in the changes in diagnostic criteria defined by the ADA Expert Group and those recommended by the WHO Consultation is that the ADA strongly recommended that the FPG could be used on its own and that in general the 2hPG need not be used. In contrast, the WHO Consultation retained the 2hPG and suggested using the FPG alone in epidemiological surveys only when circumstances prevent use of the OGTT [2, 34]. We have previously shown that a change from the use of the 2-h glucose alone to the use of the fasting glucose alone for the diagnosis of diabetes in population surveys would induce quite dramatic changes in the prevalence of diabetes in some European populations [12]. The magnitude of the change was influenced by age and obesity in the populations studied. For the overall diabetes prevalence in Europe, a change in method from defining diabetes by the 2hPG of 11.1 mmol/l or more to FPG of 7.0 mmol/l or more would increase the prevalence of diabetes from 7.2 % to 7.7 % but with a range between populations from a 26 % decrease to a 51 % increase. Among the 1665 people diagnosed diabetic either based on the FPG or on the 2hPG, only 489 (29 %) had FPG of 7.0 or more and 2hPG of 11.1 mmol/l or more.

The first aim of the present study was to evaluate the statement by the ADA Expert Committee and the WHO Consultation that a FPG of 7.0 mmol/l is "of approximately equal diagnostic significance" to that of a 2hPG of 11.1 mmol/l. We found that the FPG concentration corresponding to a 2hPG value of 11.1 mmol/l with maximised sensitivity and specificity was 6.4 mmol/l in men and 5.8 mmol/l in women. These fasting values are lower than those reported from the Pima Indians [35], the Pacific Island populations [36] and the NHANES III study [1]. We show that the FPG value optimising sensitivity and specificity was dependent on BMI, increasing from 5.8 mmol/l in lean people (BMI < 25 kg/m^2) to 6.6 mmol/l in obese people (BMI ≥ 30 kg/m^2). The mean BMI in this study was 25.9 kg/m^2 in contrast to that of Pima Indians of 31.6 kg/m^2 and Micronesians from Nauru, 33 kg/m^2 [37]. This difference in obesity may explain the difference between the results of our study and those quoted by the ADA Expert Committee [1].

We found that a cut-point of 7.8 mmol/l is highly specific (99.7 %) in identifying people without a diabetic 2hPG but the sensitivity is low (20 %). Lowering the diagnostic threshold for FPG to 7.0 mmol/l increased the sensitivity to 49 % without any major loss in specificity (98.2 %). Thus, lowering the diagnostic FPG from 7.8 to 7.0 mmol/l would be an advantage in terms of sensitivity but the low sensitivity of only 49 % raises the need for a confirmatory test, for which the 2-h post load glucose concentration would be a rational choice.

The high prevalence of microvascular [7–10] and macrovascular [38, 39] complications and the estimated median diabetes duration of at least 4 to 7 years before clinical diagnosis of diabetes [11] were the main reasons for the ADA Expert Committee recommending screening for diabetes in everybody

Table 3. Distribution of the 29108 people without previously diagnosed diabetes, according to fasting and 2-h glucose categories. The DECODE Study

		2-h glucose			Total
		Normal	IGT	Diabetic	
	Normal	21968 (75.5%)	2562 (8.8%)	316 (1.1%)	24846 (85.4%)
Fasting glucose	IFG	2020 (6.9%)	893 (3.1%)	206 (0.7%)	3119 (10.7%)
	Diabetic	276 (0.9%)	378 (1.3%)	489 (1.7%)	1143 (3.9%)
Total		24264 (83.4%)	3833 (13.2%)	1011 (3.5%)	29108 (100%)

above the age of 45 years [1]. As we have shown previously [12], only 48% of previously undiagnosed diabetic people with a 2hPG of 11.1 mmol/l or more also have a FPG of 7.0 mmol/l or more. The second aim of this analysis therefore was to test the usefulness of different stepwise screening models for diabetes using a FPG as a screening variable followed by 2-h OGTT only if the FPG was above a specified level, assuming that our DECODE population is representative of a general European population. The potential advantage of this strategy would be that the number of glucose measurements could be reduced (reducing the costs and time related to the screening process). We analysed FPG concentrations of 5.5 and 6.0 mmol/l, as cut-points for proposing a 2-h OGTT. Both these procedures would identify the majority of the diabetic people (93% and 82%, respectively) but neither of these procedures would have sufficient sensitivity to detect people with IGT, as they would only detect 69% and 29% of such people. People with IGT may be the most important target for future interventions to prevent development of overt diabetes. One recent Chinese study has shown that changes in lifestyle may reduce the progression rate to diabetes by 35–40% [40] and several ongoing trials are testing pharmacological and non-pharmacological prevention strategies (Diabetes Prevention Programme in the USA, STOP-NIDDM trial in Canada, DPS-study in Finland, EDIPS-study in Europe). It may be possible to develop screening procedures based on FPG and HbA_{1c} that would also increase the sensitivity for detection of people with IGT [41, 42] but in our study we did not have HbA_{1c} measurements. Future studies should specifically test these possibilities.

In the revised diagnostic criteria for diabetes, the FPG concentration was lowered because the prevalence of retinopathy started to increase at FPG concentrations close to 7.0 mmol/l [1]. At the same time a new category was introduced, impaired fasting glycaemia [1]. The ADA Expert Group and the WHO Consultation [2] both state that the IFG and IGT groups may not identify the same people but they suggest that both are high risk groups for the devel-

Table 4. Age adjusted mean values of cardiovascular risk factors in the 3119 people with impaired fasting glycaemia, classified according to 2-h glucose concentrations. The DECODE Study

2-h glucose classification	Normal	IGT	Diabetic	*p*-value
Age < 60 years				
Men				
Number of subjects	1309	407	61	
BMI (kg/m^2)	27.2	27.7	27.9	0.02
Systolic blood pressure (mm Hg)	146	152	152	0.001
Diastolic blood pressure (mm Hg)	85	88	91	0.001
Cholesterol (mmol/l)	6.0	6.1	6.1	0.1
Women				
Number of subjects	213	104	27	
BMI (kg/m^2)	27.3	29.2	30.9	0.001
Systolic blood pressure (mm Hg)	133	142	142	0.001
Diastolic blood pressure (mm Hg)	81	85	89	0.001
Cholesterol (mmol/l)	6.4	6.1	6.3	0.3
Age $\geq$ 60 years				
Men				
Number of subjects	348	238	69	
BMI (kg/m^2)	27.1	27.4	27.8	0.2
Systolic blood pressure (mm Hg)	148	154	157	0.002
Diastolic blood pressure (mm Hg)	84	85	86	0.1
Cholesterol (mmol/l)	6.1	6.0	6.2	0.8
Women				
Number of subjects	150	144	49	
BMI (kg/m^2)	28.5	29.6	27.8	0.03
Systolic blood pressure (mm Hg)	153	158	157	0.3
Diastolic blood pressure (mm Hg)	83	83	85	0.7
Cholesterol (mmol/l)	6.4	6.3	7.0	0.03

opment of diabetes. Although the two groups are almost of equal size, the people classified as IGT are not the same as those classified as IFG. Therefore, we compared the cardiovascular risk profile within the IFG group, subdivided on the basis of 2-h glucose concentration as normal, IGT or diabetic. Blood pressure and BMI generally increased with increasing 2-h glucose values. Based on this finding we would expect that people with isolated IFG (high fasting glucose and normal post load glucose) would have a lower mortality and lower risk of developing cardiovascular disease. Thus it is questionable whether it is rational to establish IFG as a separate, new clinical entity. Before doing so it should at least be shown that isolated IFG is associated with increased mortality or morbidity from cardiovascular disease, or that IFG has an acceptable sensitivity and specificity in predicting the subsequent development of diabetes. Otherwise we will be labelling people as being at high risk without any valid reason which raises ethical problems.

In conclusion, in 1997 the ADA revised their diagnostic criteria for diabetes, lowering the FPG value from 7.8 to 7.0 mmol/l, introducing a new category, (IFG) and recommending the use of FPG alone for the diagnosis of diabetes. In 1998 the WHO Consultation followed the ADA with respect to the two first recommendations, while they retained the use of the 75-g OGTT and the 2hPG for diagnostic purposes. We show that if the FPG were used alone, 31 % of all people with diabetes (based on fasting or 2-h glucose concentrations or both) will remain undiagnosed. Furthermore, the sensitivity and specificity of the FPG concentration in detecting a diabetic 2hPG depends on the BMI. This may explain the difference between our results and data from the United States and the Pacific Islands and makes it even more important to analyse the impact of using only the FPG for diagnosing diabetes in other regions including Asia. Finally, this study shows that fasting glucose concentrations are of very limited help in identifying people with IGT, a group where prevention of progression to overt diabetes seems to be possible. For these reasons we would strongly recommend the continued use of the 2hPG in the diagnosis of diabetes. Based on the ROC-curves as well as the cardiovascular-risk profile there is, however, good support for the lowering of the FPG value diagnostic for diabetes from 7.8 to 7.0 mmol/l.

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