Articles

Comparison of the fasting and the 2-h glucose criteria for diabetes in different Asian cohorts

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Abstract

Aims/hypothesis. The American Diabetes Association recommended that only a single fasting plasma glucose of greater than or equal to 7.0 mmol/l should be used for diagnosing diabetes in epidemiological studies and did not recommend using a 2-h oral glucose tolerance test. We evaluated the effect of diagnostic changes on the prevalence of diabetes and on the choice of subjects diagnosed with diabetes.
Methods. Existing epidemiological data collected from Asian people between 30 and 89 years of age, was re-analysed separately in 11 population-based studies ($n = 17\,666$), 6 pre-selected hyperglycaemic cohorts ($n = 12\,221$) and one suspected diabetic cohort ($n = 8\,382$).
Results. Among the 11 population-based studies, the new fasting glucose criteria resulted in an overall reduction of 1.8% in the prevalence of diabetes, which ranged from a reduction of 4.8% to an increase of 1.7% in the different studies. Of 1215 subjects diagnosed with diabetes by either criteria, only 449 met both criteria, a concordance of 37%. More than half of the diabetic subjects had isolated post-challenge hyperglycaemia and three quarters of the subjects with impaired glucose tolerance, according to the 2-h glucose criteria, were normal according to the fasting glucose criteria. Subjects diagnosed as diabetic based only on the 2-h glucose criteria were, on average, older than those with diabetes according to the fasting criteria.
Conclusion/interpretation. The fasting and the 2-h glucose criteria diagnose different groups of subjects. It would therefore be inappropriate to use the fasting glucose criteria alone for screening diabetes in Asian populations. [Diabetologia (2000) 43: 1470–1475]

Keywords Revision, diagnostic criteria, diabetes, screening, fasting glucose, 2-h oral glucose tolerance test.

In 1997 the American Diabetes Association (ADA) approved lowering the fasting plasma glucose (FPG) concentration from 7.8 mmol/l to 7.0 mmol/l for diagnosing diabetes mellitus. The ADA recommended that for epidemiological studies estimates done on the prevalence and incidence of diabetes should be based on a FPG equal to or greater than 7.0 mmol/l and they did not recommend the former standard of using the 2-h 75-g oral glucose tolerance test (OGTT) [1]. A new category, impaired fasting glucose (IFG, FPG 6.1–6.9 mmol/l), was introduced by the ADA to function as a category analogous to impaired glucose tolerance (IGT) as defined by the World Health Organisation (WHO) as based on a 2-h glucose concentration [2, 3, 4]. The WHO en-

dorsed the new fasting criteria but retained the use of the OGTT [2]. They recommended that the fasting plasma glucose, alone, could be used for epidemiological purposes if it was not possible to carry out the OGTT [2].

Since the introduction of the fasting glucose criteria, there have been concerns over the effect on the prevalence of diabetes and on the re-classification of patients. The difference between the prevalence of diabetes based on the fasting and the 2-h glucose criteria varied from −4.0% to 13.2% in the 16 European surveys in the DECODE (Diabetes Epidemiology: Collaborative analysis of Diagnostic criteria in Europe) study [5]. In subjects without previously diagnosed diabetes, the DECODE study group [6] found that among all diabetic subjects diagnosed by either the fasting or the 2-h glucose criteria, only 29% qualified as diabetic according to both criteria. For IGT and IFG the concordance rate was even lower. Age, sex and body mass index (BMI) all influenced the rate of concordance. Other studies [7–10] also found that the two criteria did not identify the same groups of subjects. As the DECODE observations differed from those in the United States and Egypt [1], we hypothesised that not only age, sex and BMI but also ethnicity could influence the relevance of diagnostic criteria for diabetes based only on fasting glucose values.

To further evaluate this hypothesis, the DECODA (Diabetes Epidemiology: Collaborative analysis of Diagnostic criteria in Asia) study was initiated. We compared the prevalence of diabetes derived from the fasting glucose values with the prevalence derived from the 2-h glucose values separately. The effects of the phenotypic characteristics of subjects were also assessed.

Subjects and methods

Cohorts and measurements. Centres that had carried out studies on the prevalence of diabetes in adult Asian people were identified and invited to participate in the DECODA study. A total of 18 studies done in 7 Asian countries and in Los Angeles and Hawaii in the United States contributed data on plasma glucose at fasting and 2-h after a 75-g oral glucose load. Of the 18 studies 11 were population-based samples [11–16]. Five studies [17–21] did a standard OGTT only on subjects who were positive at stepwise screening tests based on 2-h [17–19], fasting [20] or urine glucose measurements [21] and one study [22] on subjects who came to a hospital for a health check-up. Data from Bangladesh were taken from subjects with known or suspected diabetes based on clinical symptoms who had been admitted to a diabetic clinic for diagnostic testing. Because of the methodological differences between the centres, data were analysed separately for the three groups: the eleven population-based studies, the six pre-selected hyperglycaemic cohorts and the one suspected diabetic group in Bangladesh. Data for subjects selected from stepwise screening programmes and from the diabetic clinic in Bangladesh could not be used for prevalence estimates but they were used to analyse the concordance between the fasting and the 2-h glucose crite-

ria. Characteristics of subjects are presented for each of the 18 studies stratified by the 3 groups (Table 1).

Stepwise screening programmes were used in five studies. Subjects went on to a full OGTT if they had a positive test based on 2-h 75-g post-load glucose greater than or equal to 6.7 mmol/l in the Shougang study [18]; on 2-h glucose greater than or equal to 7.2 mmol/l after eating a 100 g steamed bun in the Hospital 301 study [19]; on fasting glucose between 5.6–7.8 mmol/l in the Kinmen study [20]; and on a positive urine glucose test in the Hiroshima study [21]. In the 12 provinces studied [17], fasting plasma samples were collected for all participants when an OGTT was carried out but fasting plasma glucose was measured only for subjects whose 2-h 75-g post-load glucose were greater than or equal to 7.8 mmol/l. The Harbin and the Shougang [18] studies were based on occupation. The Harbin study was carried out among railway workers in Harbin city and the Shougang study among employees in a steel corporation in Beijing. The Osaka [22] and the Hospital 301 [19] studies were based on subjects who came for health check-ups and most of the subjects in the Hospital 301 study were elderly army officers.

Plasma glucose concentrations, data on age, sex, date of examination, height, weight, status of known diabetes and medication for diabetes and details on the glucose assay used were requested and sent to the Diabetes and Genetic Epidemiology Unit of the National Public Health Institute in Helsinki, Finland for analysis.

Classification of subjects. Subjects not previously known to have diabetes were classified according to the WHO 1999 recommendation [2] as follows: ADA fasting glucose criteria [1] was adopted and the WHO 1985 2-h glucose criteria [3] was retained. First, fasting plasma glucose less than 6.1, 6.1 to 6.9 and greater than or equal to 7.0 mmol/l defined subjects as normal, IFG and diabetic, respectively. Second, plasma glucose at 2 h after a 75-g oral glucose load less than 7.8, 7.8 to 11.0 and greater than or equal to 11.1 mmol/l classified subjects as normal glucose tolerant, IGT and diabetic, respectively.

Subjects previously known to be diabetic (including those receiving insulin or oral hypoglycaemic agents) were also identified.

Statistical analysis. All analyses were conducted with SPSS for Windows, version 9.0.1. The prevalence of diabetes was calculated according to either the fasting glucose criteria or the 2-h glucose criteria. The differences between classifications were compared by chi-squared tests. A general linear model was applied, when age and centre-adjusted means were compared. A p value less than 0.05 was considered to be statistically significant.

Results

The characteristics of the DECODA study cohorts are shown in Table 1 for each centre and they are classified into three different groups: population-based studies, pre-selected hyperglycaemic populations and the suspected diabetic subjects in the Dhaka, Bangladesh study. Subjects in the analysis were 30 to 89 years old at the time of glucose sampling and had both fasting and 2-h glucose concentrations determined or were previously diagnosed with diabetes.

The prevalence of previously diagnosed and undiagnosed diabetes and the absolute change in the prevalence of newly diagnosed diabetes according to

Table 1. Characteristics of the DECODA study populations

Survey site	Year	n	% Men	Age (years)	BMI (kg/m^2)	Ethnic groups
Population-based studies						
Dombivli, India	1998–99	520	54	48 ± 12 (31–80)	24.5 ± 3.4	Indian
Harbin, China	1998	697	73	44 ± 3 (41–58)	23.9 ± 3.3	Chinese
Shunyi, China	1997–98	1283	41	53 ± 11 (31–89)	25.1 ± 3.7	Chinese
Jakarta, Indoneisa	1992–93	588	47	47 ± 11 (30–87)	23.4 ± 4.1	Jawa
Madras (Chennai), India	1993–95	1275	53	45 ± 10 (30–84)	23.2 ± 4.2	Indian
Beijing, China	1997	1540	38	58 ± 11 (39–89)	25.1 ± 3.6	Chinese
Hisayama, Japan	1988	2480	43	57 ± 10 (40–79)	22.9 ± 3.1	Japanese
Singapore	1992	2481	47	44 ± 10 (30–69)	23.8 ± 4.1	Chinese, Malay, Indian
Funagata, Japan	1990–92	2528	44	60 ± 10 (40–87)	23.7 ± 3.2	Japanese
Ojika, Japan	1991, 1996	1545	40	58 ± 12(30–85)	23.1 ± 2.9	Japanese
Hawaii & L.A., USA	1980–96	2729	43	60 ± 13 (30–89)	23.5 ± 3.4	Japanese-Americans
Total		17666	45	54 ± 13 (30–89)	23.7 ± 3.6	
Pre-selected hyperglycaemic populations						
Shougang, China	1992–93	3224	69	46 ± 9 (30–80)	25.6 ± 3.3	Chinese
12 provinces, China	1995–96	608	43	53 ± 11 (30–74)	25.2 ± 3.9	Chinese
Kinmen, Taiwan	1991–94	1456	53	52 ± 13 (30–88)	24.1 ± 3.4	Chinese
Hiroshima, Japan	1985–86	823	44	59 ± 10 (31–87)	22.7 ± 3.3	Japanese
Osaka, Japan	1984–96	5466	74	54 ± 10 (30–86)	23.7 ± 3.0	Japanese
Hospital 301, China	1997	644	96	71 ± 8 (46–88)	25.0 ± 3.1	Chinese
Total		12221	68	53 ± 12 (30–88)	24.3 ± 3.3	
Suspected Diabetic subjects						
Dhaka, Bagladesh	1980–1995	8382	73	49 ± 11 (30–85)	23.3 ± 3.9	Bengali

Table 2. Prevalence of diabetes and changes in prevalence in the 18 DECODA studies

Survey site	No.	Prevalence of diabetes (%)				Changes in prevalence (%) (95% CI) Fasting – 2-hour
		Known	Fasting[1]	2-hour[2]	Either or both[3]	
Population based studies						
Dombivli, India	520		7.7	6.0	9.0	1.7 (-1.4 to 4.9)
Harbin, China	697	2.9	2.2	0.7	2.4	1.4 (0.2 to 2.7)
Shunyi, China	1283	2.9	4.3	4.7	6.3	–0.4(-2.0 to 1.2)
Jakarta, Indoneisa	588	6.0	4.1	4.8	6.8	–0.7 (-3.1 to 1.7)
Madras (Chennai), India	1275	12.6	5.9	7.3	9.1	–1.4 (-3.4 to 0.6)
Beijing, China	1540	7.3	4.9	6.4	7.9	–1.5 (-3.2 to 0.2)
Hisayama, Japan	2480	7.7	3.3	4.8	6.2	–1.5 (-2.6 to –0.4)
Singapore	2481	6.2	5.4	6.9	8.1	–1.5 (-2.9 to –0.1)
Funagata, Japan	2528	0.8	2.1	4.3	5.0	–2.2 (-3.2 to –1.2)
Ojika, Japan	1545		2.5	4.9	6.0	–2.4 (-3.7 to –1.0)
Hawaii & L.A., USA	2729	7.1	2.9	7.7	8.0	–4.8 (-6.0 to –3.5)
Total	17666	5.2	3.8	5.6	6.9	–1.8 (-2.3 to –1.4)
Pre-selected hyerglycaemic populations						
Shougang, China	3224	9.3	16.8	17.1	21.6	–0.3 (-2.3 to 1.7)
12 provinces, China	608		26.8	30.3	37.3	–3.5 (-9.5 to 2.6)
Kinmen, Taiwan	1456		7.0	10.6	12.6	–3.6 (-5.7 to –1.4)
Hiroshima, Japan	823	10.2	18.3	22.6	25.8	–4.3 (-8.6 to 0.1)
Osaka, Japan	5466		7.5	11.8	13.0	–4.3 (-5.5 to –3.2)
Hospital 301, China	644		8.7	23.6	25.9	–14.9 (-19.3 to –10.5)
Total	12221		11.6	15.3	18.0	–3.7 (-4.6 to –2.8)
Suspected diabetic subjects						
Dhaka, Bagladesh	8382		78.7	78.2	80.3	0.6 (-2.1 to 3.3)

[1] Newly diagnosed diabetes defined by fasting plasma glucose ≥ 7.0 mmol/l only
[2] Newly diagnosed diabetes defined by 2-h plasma glucose ≥ 11.1 mmol/l only
[3] Newly diagnosed diabetes defined by either fasting or 2-h glucose criteria

the fasting and the 2-h glucose criteria are presented for each study (Table 2). Among population-based studies, the absolute changes in prevalence varied between + 1.7% and –4.8% with an overall reduction of 1.8% but when the change in prevalence was cal-culated as a percentage of the 2-h prevalence, it var-ied between a 200% increase (Harbin) and a 62% decrease (Hawaii and Los Angeles).

Of the 995 subjects with 2-h glucose greater than or equal to 11.1 mmol/l, 546 (55%) had non-diabetic

Table 3. Distribution of subjects according to the 2-h and the fasting glucose categories in people not previously diagnosed as diabetic from the DECODA population-based studies

Fasting glucose (mmol/l)	2-h glucose (mmol/l)			
	< 7.8	7.8–11.0	≥ 11.1	Total
< 6.1	12 443 (74.3)	1984 (11.9)	291 (1.7)	14 718 (87.9)
6.1–6.9	621 (3.7)	476 (2.8)	255 (1.5)	1352 (8.1)
7.0–7.7	63 (0.4)	86 (0.5)	146 (0.9)	295 (1.8)
≥ 7.8	38 (0.2)	33 (0.2)	303 (1.8)	374 (2.2)
Total	13 165 (78.6)	2579 (15.4)	995 (5.9)	16 739 (100)

Figures are numbers (percentages of total)

fasting glucose values (Table 3); of the 669 subjects with fasting glucose greater than or equal to 7.0 mmol/l, 220 (33%) had non-diabetic 2-h values (Table 3); of the 1 215 subjects diagnosed with diabetes on either criteria, only 449 (37%) met both the fasting and 2-h glucose criteria. An even larger discrepancy was observed for the categories of IFG and IGT. Among the 2 579 IGT subjects (2-h glucose between 7.8 and 11.0 mmol/l), 77% had a normal fasting plasma glucose (< 6.1 mmol/l).

Agreement of the two diagnostic criteria for newly diagnosed diabetes was higher in the selected cohorts. A concordance of 95% was observed in the subjects who were detected or suspected to have diabetes in Bangladesh and 50% in the pre-selected hyperglycaemic cohorts. The lowest agreement (37%) was observed in the asymptomatic diabetic subjects in the random population-based studies.

For subjects diagnosed diabetic by the 2-h glucose concentration compared with those diagnosed by a fasting glucose concentration, no difference was found between sexes (44% women and 51% men, $p = 0.19$). The group of women was, however, older (Table 4). The centre-adjusted mean age was 59 and 53 years in men ($p < 0.001$) and 60 and 56 years in women ($p < 0.001$). Men diagnosed diabetic by the 2-h glucose concentration had a higher mean BMI than men diagnosed by the fasting criteria; however, among the women, there was no difference in BMI between the different diabetic groups.

This relation did not change when data from Harbin was excluded, where there was an extremely low prevalence of diabetes according to the 2-h glucose criteria.

Discussion

The change in diagnostic procedure has brought a complex and variable effect on the prevalence of diabetes and on the subjects diagnosed. Overall, the prevalence in the general Asian cohorts did not change substantially but the variation between studies was considerable. This variability is in keeping with findings from the analysis of population-based studies in Europe (DECODE) [5, 6] and in southern hemisphere island populations [7]. This raises concern about the validity of diagnostic criteria and stresses the importance of studying the existing epidemiological data before global, uniform recommendations are justified.

A far more important consequence is that the fasting and the 2-h glucose criteria did not identify the same subjects as diabetic. In this study, one third of the diabetic subjects and more than three quarters of the subjects with IGT according to the 2-h glucose criteria would be classified as normal if only the fasting glucose concentration was used.

Age was a major determinant in the disagreement in subject classification. The 2-h glucose criteria were more likely to diagnose diabetes among the elderly. This was also apparent from the observations among the elderly in the Hospital 301 study in China [19], as well as from the analysis related to age in the entire population-based sample of our study. This is consistent with recent findings in studies on older Americans [8, 23] and in the southern hemisphere island population studies [7]. The DECODE study in Europe [5] found that the middle-aged subjects were more likely to be diagnosed diabetic by the fasting glucose criteria. These data support the hypothesis that the discordance in classification of subjects results in a change in the diabetic phenotype.

Studies in the European and in the southern hemisphere island populations [5–7] found that the fasting glucose criteria were more likely to diagnose obese diabetic subjects but this was not the case among Asian people. Diabetic men who met the fasting glucose criteria in our study were leaner than men diagnosed by 2-h or by both glucose criteria, whereas no such difference was observed among women. The difference between studies could be attributed to the substantial difference in the mean BMI and in the definition of obesity between our study and other studies. Obesity is not common among Asian people. Less than 5% of the newly diagnosed diabetic subjects in this study had a BMI greater than or equal to 30 kg/m^2, whereas it accounted for 45% of the newly diagnosed diabetic cohort from the southern hemisphere islands [7] and 32% in the European cohorts [5]. This lean group of people with Type II (non-insulin-dependent) diabetes mellitus should have been

Table 4. Characteristics of subjects according to the fasting and the 2-h glucose criteria for the diagnosis of diabetes in people without previously diagnosed diabetes from DECODA population-based studies

	Men				p value	Women				p value
	Not diabetic	Diabetic				Not diabetic	Diabetic			
		Fasting only	2-h only	Both			Fasting only	2-h only	Both	
No.	6945	113	241	204		8579	107	305	245	
Age (years)	53 (0.15)	53 (1.18)	59 (0.81)	55 (0.88)	< 0.001	54 (0.13)	56 (1.18)	60 (0.70)	58 (0.78)	< 0.001
Body mass index (kg/m^2)	23.5 (0.04)	24.0 (0.31)	25.2 (0.21)	25.0 (0.23)	< 0.001	23.6 (0.04)	25.5 (0.36)	25.4 (0.21)	26.1 (0.24)	< 0.001

Data are given as means (SEM), adjusted for age and centres

taken into account when the diagnostic criteria were revised.

The concordance of diagnostic classification by the two tests is dependent on where the tests were administrated. An excellent agreement was found in the Dhaka, Bangladesh study where all of the subjects who were referred to OGTTs had been diagnosed with diabetes or suspected to be diabetic. In the pre-selected hyperglycaemic groups with asymptomatic hyperglycaemia, the agreement was better than in the general population-based studies but still weak. This indicates that the more severe the hyperglycaemia, the better the agreement between the fasting and the 2-h glucose criteria. It might be appropriate to use the fasting glucose test alone in subjects with clinical symptoms of diabetes to confirm their diabetes. It would be inappropriate, however, to only use the fasting glucose test in the general Asian population for epidemiological purposes, or in an Asian cohort with slightly higher glycaemia but without any symptoms of diabetes because a large proportion of subjects diagnosed diabetic by the 2-h glucose criteria would not be identified. Among Asian people with diabetes, it is common for a subject to be diagnosed as diabetic by 2-h oral glucose tolerance test but considered normal according to fasting glucose concentrations. In 1999 the WHO recommended retaining the use of 2-h OGTT for epidemiological purposes [2], this appears to be particularly important for the Asian population.

This study provides further evidence to support the previous findings that the fasting and the 2-h glucose criteria diagnose different groups of people. Among Asian people, who are usually relatively lean, 2-h glucose seems to be a particularly important diagnostic tool. Because subjects with post-challenge hyperglycaemia either isolated or combined with fasting hyperglycaemia have a high risk of developing macrovascular disease and early death [24–25], identification of these subjects is important. Therefore, it is not justified to use fasting glucose test alone for screening diabetes among Asian people.

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