

Comparing Fasting Plasma Glucose against Two-hour Post-load Glucose Concentrations for the Diagnosis of Diabetes Mellitus and Glucose Intolerance in Singaporean Hospital Patients

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Abstract

Introduction: Several studies have assessed the impact of the 1997 American Diabetes Association (ADA) recommendation, of using fasting plasma glucose (FPG) concentration, to diagnose diabetes mellitus in population-based cohorts. However, data concerning the impact of this recommendation in the hospital setting are limited. As the performance characteristics of diagnostic tests vary depending on the prevalence of diabetes in the population studied, we have examined the clinical impact of adopting the ADA recommendations in comparison to the traditional 2-hour post-load glucose (2HPG) concentration used by the World Health Organisation (WHO) in diagnosing diabetes and other categories of glucose intolerance in Singaporean hospital patients. **Materials and Methods:** We analysed the results of the standard 75g oral glucose tolerance test (OGTT) performed on 625 patients in our hospital from 1994 to 1999. **Results:** The prevalence of diabetes amongst these 625 patients was 36.8% (230) based on the ADA recommendation of using FPG, 42.8% (263) on using the 2HPG and 52.0% (325) on using the full 1998 WHO criteria. The degree of agreement (κ) in establishing the diagnosis of diabetes between the FPG and 2HPG cut-offs was 0.48. Ninety-five (15.2%) individuals had diabetes based on the 2HPG alone, 62 (9.9%) based on the FPG alone and 168 (26.9%) based on both the FPG and 2HPG. Eighty-six (13.8%) individuals had impaired fasting glucose (IFG) and 123 (19.7%) had impaired glucose tolerance (IGT). The κ -value between IFG and IGT was 0.08. **Conclusion:** Fasting plasma glucose concentration was an inadequate parameter in diagnosing diabetes and intermediate categories of glucose intolerance in our cohort of subjects. Our findings suggest that the OGTT remains an important diagnostic tool for classifying glucose tolerance in our hospital patients.

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Key words: ADA & WHO diagnostic criteria, Impaired fasting glucose, Impaired glucose tolerance

Introduction

Prior to 1997, the diagnosis of diabetes mellitus in asymptomatic individuals was based upon the 1985 World Health Organisation (WHO) diagnostic criteria in which, utilising the 75g oral glucose tolerance test (OGTT), diabetes was defined either by a fasting plasma glucose (FPG) concentration of ≥ 7.8 mmol/L or by a glucose concentration of ≥ 11.1 mmol/L 2 hours after the glucose challenge, or both.¹ Of the two cut-off levels, the 2-hour post-load glucose (2HPG) value is especially important as it positively correlates with the future risk of developing microvascular complications of diabetes.¹⁻³

However, since 1985, it has been shown that equivalent thresholds could be set for FPG concentration to predict

similar future microvascular risk.^{4,5} Hence, because of its simplicity and to encourage diabetes screening, the American Diabetes Association (ADA) in 1997 recommended using the FPG concentration to diagnose diabetes without the need for the OGTT.⁵ Although the ADA still includes the 2HPG value of the OGTT in its formal criteria, the routine use of the 2HPG value was not recommended as it was deemed to be inconvenient, costly and more time-consuming than the FPG.⁵

In addition, the ADA recommended a reduction in the FPG cut-off value from 7.8 mmol/L to 7.0 mmol/L as the latter was noted to correlate best with a 2HPG of 11.1 mmol/L. Moreover, it was felt that a lower FPG cut-off would reduce the number of undiagnosed asymptomatic

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diabetic subjects in many populations.⁵ A new intermediate category called impaired fasting glucose (IFG) was introduced, defined as a FPG concentration of 6.1 to 6.9 mmol/L.⁵ Whilst accepting the lower FPG diagnostic value of 7.0 mmol/L, the WHO Consultation Group in 1998 nevertheless advocated retaining the 2HPG value of ≥ 11.1 mmol/L to diagnose diabetes.⁶

Since 1997, a number of epidemiological studies, evaluating various populations differing in nationality and ethnicity, have detected a disagreement between the ADA recommendations and the WHO criteria. It has been shown that the diagnosis of diabetes mellitus would be missed in a substantial number of subjects if the ADA recommendations are followed.⁷⁻¹¹ Most of these studies have evaluated population-based cohorts and data concerning the impact of the different diagnostic criteria on hospital populations are lacking. We have, therefore, reviewed the OGTTs performed in our hospital patient population to study the clinical impact of adopting the 1997 ADA recommendation of using the FPG in comparison to the traditional WHO criteria of using the 2HPG in diagnosing diabetes mellitus as well as intermediate categories of glucose intolerance.

Materials and Methods

We obtained the results of all 75g OGTTs (as defined by the WHO)¹ performed in our hospital from 1994 to 1999 on 650 subjects who had no previous history of diabetes. These subjects had been referred for an OGTT because of the presence of risk factors for glucose intolerance including a positive family history of diabetes, previous history of gestational diabetes, elevated random blood glucose level or obesity. The medical records of these subjects were reviewed. OGTTs performed on subjects suffering from concomitant illnesses were excluded to reduce possible confounding bias arising from stress-induced hyperglycaemia. Subjects receiving medication that might influence glucose metabolism such as glucocorticoids were excluded. Venous plasma glucose samples were estimated at 0 and 2 hours following a 75g glucose load using the Beckman CX-5 analyser. All individuals were classified accordingly on the basis of their venous plasma glucose concentration as defined in Table I.

Statistical calculations were performed using SPSS version 9.01 for Windows. Quantitative data are expressed as mean $\pm$ SD. Differences between means were assessed using one-way ANOVA. Statistical significance was set at $P < 0.05$. Cohen's kappa (κ) was used to assess the measure of agreement between FPG and 2HPG as well as between IFG and IGT on the diagnosis of diabetes as well as intermediate states of glucose intolerance respectively. A value of 1 indicates perfect agreement whereas a value of 0 indicates that the agreement is no better than chance. A

TABLE I: CLASSIFICATION OF SUBJECTS BASED ON THE FASTING PLASMA GLUCOSE (FPG) AND 2-HOUR POST-LOAD GLUCOSE (2HPG) VALUES OF THEIR ORAL GLUCOSE TOLERANCE TESTS

1997 ADA recommendations*	1985 WHO criteria**
Normal if FPG ≤ 6.0 mmol/L	Normal if 2HPG < 7.8 mmol/L
Impaired fasting glucose if FPG = 6.1-6.9 mmol/L	Impaired glucose tolerance if 2HPG = 7.8-11.0 mmol/L
Diabetes if FPG ≥ 7.0 mmol/L	Diabetes if 2HPG ≥ 11.1 mmol/L

ADA: American Diabetes Association; WHO: World Health Organisation

* Using FPG regardless of 2HPG

** Using 2HPG regardless of FPG

value below 0.40 indicates poor agreement.¹² Sensitivity, specificity, positive and negative predictive values were calculated using standard formulae.¹³

Results

Patient Characteristics (Tables IIa and IIb)

A total of 650 OGTT results were obtained. After excluding 25 of these (unsuitable because of OGTT being done in the presence of concomitant illnesses, in subjects with known diabetes or on medications), the OGTT values of 625 individuals (350 males and 275 females) were included for analysis. The mean age was 49.9 ± 14.5 years. The mean FPG and 2HPG values in these 625 subjects were 7.3 ± 3.5 mmol/L and 11.2 ± 5.8 mmol/L, respectively. Comparison of the means of the FPG and 2HPG between races revealed no statistically significant difference.

Diagnosis of Diabetes Mellitus (Table III and Fig. 1)

Table III shows the distribution of the subjects, based on the results of the OGTT, classified according to the ADA

TABLE IIa: BASE-LINE CHARACTERISTICS OF ALL 625 SUBJECTS

Total number	625
Age in years (mean $\pm$ SD; range)	49.9 ± 14.5 ; 16-83
Male	350 (56%)
Female	275 (44%)

TABLE IIb: ETHNIC DISTRIBUTION OF THE STUDY POPULATION

	Number	FPG (mmol/L)	2HPG (mmol/L)
Chinese	443	7.2 ± 3.3	11.2 ± 5.9
Malay	105	7.6 ± 3.8	10.7 ± 5.5
Indian	61	7.5 ± 3.4	11.5 ± 5.8
Other races	16	9.0 ± 5.2	12.8 ± 5.8
Total	625	7.3 ± 3.5	11.2 ± 5.8

2HPG: 2-hour post-load glucose; FPG: fasting plasma glucose

Data are presented as means $\pm$ SD

TABLE III: DISTRIBUTION OF SUBJECTS BASED ON OGTT RESULTS CLASSIFIED ACCORDING TO THE ADA AND THE 1985 WHO CRITERIA

1985 WHO criteria (using 2HPG regardless of FPG, in mmol/L)	ADA criteria (using FPG regardless of 2HPG, in mmol/L)			Total
	Normal (<6.0)	IFG (≥ 6.1 & <7.0)	Diabetes (≥ 7.0)	
Diabetes (≥ 11.1)	48 (7.7%)*	47 (7.5%)*	168 (26.9%)*	263 (42.1%)
IGT (≥ 7.8 & <11.1)	81 (13.0%)	24 (3.8%)	18 (2.9%)*	123 (19.7%)
Normal (<7.8)	180 (28.8%)	15 (2.4%)	44 (7.0%)*	239 (38.2%)
Total	309 (49.5%)	86 (13.7%)	230 (36.8%)	625

2HPG: 2-hour post-load glucose; ADA: American Diabetes Association; FPG: fasting plasma glucose; IFG: impaired fasting glucose; IGT: impaired glucose tolerance; OGTT: oral glucose tolerance test; WHO: World Health Organisation

* Subjects who are diabetic by the 1998 WHO criteria using either FPG ≥ 7.0 mmol/L or 2HPG ≥ 11.1 mmol/L or both.

and the 1985 WHO criteria. The prevalence of diabetes was 36.8% (230/625) by the ADA recommendation of using the FPG and 42.1% (263/625) by the WHO criteria of using the 2HPG regardless of the FPG. The prevalence of diabetes was higher at 52.0% (325/625) on using either the FPG or the 2HPG or both, as advocated by the 1998 WHO Consultation Group (Table IV).⁶

Of the 325 subjects with diabetes, 168 satisfied both the ADA recommendation of using the FPG and the 2HPG WHO criteria, with the degree of agreement (κ) between FPG and 2HPG being 0.48 for diagnosing diabetes mellitus (Fig. 1). Among the 263 subjects who had diabetes based on the 2HPG WHO criteria, 95 (36.1%) had a FPG concentration below 7.0 mmol/L. On the other hand, 62

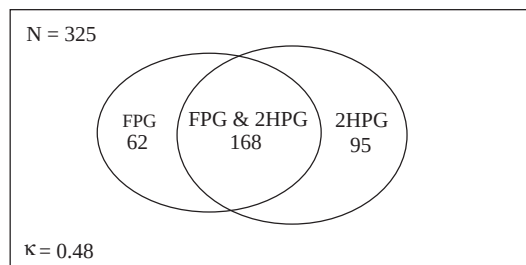
(26.9%) out of the 230 subjects, who had diabetes according to the ADA recommendation of a FPG concentration greater than 7.0 mmol/L, failed to reach the 2HPG of ≥ 11.1 mmol/L. The 2HPG WHO criterion diagnosed diabetes mellitus in 48 out of 309 (15.5%) subjects who would have been labelled as “normal” based on the ADA recommendation. Similarly, the ADA recommendation re-classified 44 subjects who had a normal 2HPG to have diabetes mellitus. Using the 2HPG WHO criteria as a reference, a FPG ≥ 7.0 mmol/L had a sensitivity of 64% and specificity of 83% in diagnosing diabetes mellitus with positive and negative predictive values of 73.0% and 75.9%, respectively.

Diagnosis of Impaired Glucose Tolerance and Impaired Fasting Glucose (Table III and Fig. 2)

Eighty-six individuals had IFG according to the ADA criterion, while 123 had impaired glucose tolerance (IGT) according to the WHO criteria. Out of the 86 subjects classified as having IFG by the ADA criterion, 47 (54.7%) had frank diabetes according to the WHO criteria. In contrast, the ADA criterion re-assigned 18 out of 123 (14.6%) individuals with IGT as being diabetics. The degree of agreement (κ) between FPG and 2HPG was 0.08 for the diagnosis of intermediate states of glucose metabolism, with 24 individuals satisfying both sets of criteria (Fig. 2).

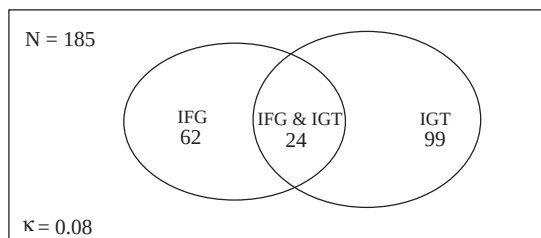
Discussion

Using a lowered cut-off point for FPG (from 7.8 mmol/L to 7.0 mmol/L) without the routine need for the OGTT was proposed by the ADA in 1997 to facilitate the diagnosis of diabetes in a practical and easy manner.⁵ A FPG of 7.0 mmol/L has been reported to correlate with a 2HPG of 11.1 mmol/L⁴ and hence, using the FPG alone was considered to be sufficient for the diagnosis of diabetes mellitus. The performance of the FPG value of 7.0 mmol/L in establishing the diagnosis of diabetes has been assessed in Asian populations as well. In a study of 865 Singaporean adults, Lee and Fook-Chong¹⁴ supported the use of a FPG cut-off



FPG: fasting plasma glucose concentration ≥ 7.0 mmol/L
2HPG: 2-hour post-load glucose concentration ≥ 11.1 mmol/L

Fig. 1. Distribution of subjects diagnosed to have diabetes mellitus.



IFG: impaired fasting glucose defined as fasting plasma glucose concentration ≥ 6.1 mmol/L and <7.0 mmol/L
IGT: impaired glucose tolerance defined as 2-hour post-load glucose concentration ≥ 7.8 mmol/L and <11.1 mmol/L

Fig. 2. Distribution of glucose intolerance categories.

TABLE IV: DIAGNOSTIC CRITERIA FOR DIABETES MELLITUS AND OTHER CATEGORIES OF HYPERGLYCAEMIA

1997 American Diabetes Association (ADA) criteria	
1. Diabetes mellitus:	Symptoms of diabetes plus casual plasma glucose concentration ≥ 11.1 mmol/L. Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia and unexpected weight loss, or FPG ≥ 7.0 mmol/L. Fasting is defined as no caloric intake for at least 8 hours, or 2HPG ≥ 11.1 mmol/L during an OGTT. The test should be performed as described by the WHO
2. Impaired fasting glucose (IFG):	FPG ≥ 6.1 mmol/L and < 7.0 mmol/L 2HPG < 7.8 mmol/L The third measure (OGTT) is not recommended for routine clinical use. (From Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 1997; 20:1183-97.)
1998 World Health Organisation (WHO) criteria (based on plasma venous samples)	
1. Diabetes mellitus:	FPG ≥ 7.0 mmol/L or 2HPG ≥ 11.1 mmol/L or both
2. Impaired glucose tolerance (IGT):	FPG < 7.0 mmol/L and 2HPG ≥ 7.8 mmol/L and < 11.1 mmol/L For epidemiological or population screening purposes, the FPG or 2HPG after 75g OGTT may be used alone. (From Alberti KGMM, Zimmet PZ for the WHO consultation. Definition, diagnosis, and classification of diabetes mellitus and its complications. Part I. Diagnosis and classification of diabetes mellitus. Provisional report of a WHO consultation. Diabet Med 1998; 15:539-53.)

value of 7.0 mmol/L as it yielded a specificity of 98.3%, with a positive predictive value of 91.8% in detecting diabetes. The new FPG value also found support in another study from Thailand which included 496 subjects at risk of developing diabetes, where it yielded a 100% positive predictive value in diagnosing diabetes mellitus.¹⁵

However, a number of epidemiological studies have demonstrated a substantial disagreement between the ADA and the WHO criteria in diagnosing diabetes mellitus.⁷⁻¹¹ Based on the ADA recommendations, the European DECODE Study (diabetes epidemiology: collaborative analysis of diagnostic criteria in Europe) showed that, when compared to the 2HPG WHO criteria, the changes to the prevalence of diabetes mellitus varied from -4.0% to +13.2%, depending on the ethnic origin and phenotype [age, sex and body mass index (BMI)] of its subjects.⁷ Other epidemiological studies have also found a tendency for the FPG value of 7.0 mmol/L to under-diagnose diabetes in Malaysians⁸ (-1.8%), Hong Kong Chinese⁹ (-3.6%), New Zealanders¹⁰ (-9.1%) and Mexicans¹¹ (-6.9%). Concordance for establishing the diagnosis of diabetes between the ADA recommendation of using the FPG and the 2HPG WHO criteria was only 28% in the DECODE study, 41.4% in the study from Hong Kong⁹ and 47.8% in the study from New Zealand.¹⁰

Contrary to these epidemiological studies, our study is

focused on a hospital-based population. The prevalence of diabetes in our cohort was lower by 6.0% on using the FPG as recommended by the ADA compared to using the 2HPG advocated by the WHO. The marked discrepancy between the 2 diagnostic methods is shown by the low κ value of 0.48. Instead of uncovering diabetes in more people, the use of FPG alone resulted in 29.2% (95/325) of our diabetics remaining undetected.

Our findings are comparable to other studies examining similar high-risk populations. A study by Puavilai et al¹⁶ from Thailand, on 1051 subjects with risk factors for glucose intolerance, revealed that the prevalence of diabetes was 17.5% less with 40.8% of diabetics remaining undetected on using the FPG as recommended by the ADA compared to the 2HPG WHO criteria. Costa et al¹⁷ found a reduction of 1.5% in the prevalence of diabetes in a similar group of 970 Spanish subjects, with the FPG cut-off being unable to detect 17.4% of the diabetics. On using the FPG, Ko et al¹⁸ reported a reduction of 8.1% in the prevalence of diabetes in a study on 2877 Hong Kong Chinese, while a reduction in prevalence of 14.7% was noted by Davies et al¹⁹ in a study on 154 high-risk British subjects.

The sensitivity and specificity of FPG in our cohort of patients for diagnosing diabetes mellitus of 64% and 83%, respectively, approach the sensitivity and specificity figures

of 57.7% and 97.4%, respectively, as reported by Puavilai et al¹⁶ and 57.3% and 98.4%, respectively, in the study of Ko et al.¹⁸ The positive predictive value of 73.0% for a FPG of 7.0 mmol/L in detecting diabetes in our cohort is lower when compared to the figure of 94% reported by Puavilai et al. However, the negative predictive value of 75.9% in our study is very similar to that of 76.4% found in the study from Thailand. These differences are probably due to inter-cohort differences.

It is interesting to note the discrepancy between the ADA recommendation of using a FPG cut-off of 7.0 mmol/L and the 2HPG WHO criteria in diagnosing diabetes mellitus in epidemiological studies as well as in studies including high-risk subjects, with a substantial number of subjects with diabetes in either setting remaining undetected on using the FPG cut-off. Clearly, the FPG and the 2HPG do not identify the same group of individuals. The reason for the discrepancy between the 2 criteria is unclear. The DECODE study suggested that the disagreement could be attributed to differences in age and BMI, with the WHO criteria diagnosing diabetes in lean individuals in contrast to the ADA recommendation identifying diabetes in middle-aged obese persons. However, Costa et al¹⁷ failed to demonstrate a similar effect in their cohort of 970 high-risk subjects. We were unable to assess the impact of BMI on the discrepancy between the two different sets of diagnostic criteria because of the non-availability of BMI in all the study subjects.

The lack of concordance between the ADA recommendations and the WHO criteria extends to the categories of IFG and IGT as well, with 80.5% of our subjects with IGT being classified either as normal fasting glycaemia (NFG) or as diabetics on using the ADA recommended FPG cut-off values. Previous epidemiological studies have shown a marked discordance between IFG and IGT. In a recent survey on 470 Singaporeans with borderline hyperglycaemia, Lim et al²⁰ reported a poor degree of agreement (κ) between IFG and IGT of only 0.25. Wat et al⁹ reported a concordance rate of 9.6% in Hong Kong Chinese, Gomez-Perez et al¹¹ found a concordance rate of 37% in Mexicans, and Park et al²¹ reported a concordance rate of 31.3% in Koreans. The poor degree of agreement (κ) of only 0.08 in our study is comparable to the reported low concordance rates of 20.7%¹⁷ and 16.7%¹⁶ in studies among high-risk cohorts from Spain and Thailand, respectively. It must be noted that the prevalence estimates of diabetes mellitus, IFG and IGT in our study cohort are derived from results of testing on a single occasion and they might differ if subjects were to undergo a second test.

The discrepancy between the ADA and the WHO criteria in identifying subjects with IGT and IFG has important

implications. There is evidence to suggest that IGT is a more sensitive predictor of type 2 diabetes compared to IFG.²² Moreover, the role of IGT as a marker for cardiovascular risk is well established. In the Whitehall study, cardiovascular mortality among people with IGT was twice that of normal controls during 20 years of follow-up.²³ Although a recent study on Singaporeans with abnormal glucose tolerance suggests that the adverse cardiovascular risk profiles in subjects with either IFG or IGT are similar,²⁰ larger studies are necessary to establish the exact risk of individuals with IFG with regards to cardiovascular disease.

Of greater worry is the implication that the ADA criteria may fail to identify individuals who are at increased risk of death. Data from the DECODE study indicated that the 2HPG concentration, and not the FPG concentration, was associated with higher long-term mortality.⁷ Similar findings have been reported recently following a subset analysis of the population-based Hoorn Study. Subjects diagnosed to be diabetic by the 2HPG WHO criteria had an increased mortality risk (16.1% versus 11.9% for normal subjects), a finding that was not observed if the ADA recommended FPG criteria of 7.0 mmol/L was used instead (13.0% versus 12.1%).²⁴ As such, it may be prudent to continue to do an OGTT in high-risk individuals with a FPG of below 7.0 mmol/L to avoid missing a diagnosis of diabetes mellitus with its attendant risk of long-term complications.

Conclusion

Our findings indicate that FPG concentration of 7.0 mmol/L, as advocated by the ADA, is an insensitive parameter for the diagnosis of diabetes mellitus and glucose intolerance in our hospital patients. Our data suggest that it would be prudent to continue to do an OGTT in high-risk individuals with a FPG of below 7.0 mmol/L to maximally identify patients with any form of glucose intolerance.

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