The Effect of Lowering the Threshold for Diagnosis of Impaired Fasting Glucose

So Hun Kim,[1] Wan Sub Shim,[1] Eun A Kim,[1] Eun Joo Kim,[1] Seung Hee Lee,[1] Seong Bin Hong,[1] Yong Seong Kim,[1] Shin Goo Park,[2] Jong Whan Lim,[2] Hun-Jae Lee,[3] and Moonsuk Nam[1,4]

[1]Departments of Internal Medicine, [2]Occupational and Environmental Medicine, [3]Preventive and Social Medicine, [4]Center for Advanced Medical Education (BK 21 project), Inha University College of Medicine, Incheon, Korea.

Purpose: The aim of this study was to evaluate the effect of lowering the fasting plasma glucose (FPG) criteria for impaired fasting glucose (IFG) on the prevalence of IFG and the risk for the development of diabetes associated with IFG in Koreans. **Materials and Methods:** A total of 7,211 subjects who had normal glucose tolerance (NGT) or IFG were recruited. Subjects were evaluated at baseline and after two years follow up. Clinical data including total cholesterol, FPG and blood pressure were examined. **Results:** Lowering the criteria for IFG from 6.1 mmol/L (110 mg/dL) to 5.6 mmol/L (100 mg/dL) increased the prevalence of IFG from 6.6% (494 subjects) to 24.4% (1829 subjects). After the 2 years follow up period, 91 subjects (1.3%) developed diabetes. Twenty one (0.3%) subjects developed diabetes among 5,382 NGT subjects and 70 (3.8%) subjects developed diabetes among 1,829 IFG (5.6 - 7.0 mmol/L) subjects. Lowering the IFG threshold from 6.1 mmol/L to 5.6 mmol/L resulted in a 18.4% decrease in specificity and 23.9% increase in sensitivity for predicting diabetes. The baseline FPG for predicting the development of diabetes after 2 years at a point on the receiver operating characteristic curve that was closest to the ideal 100% sensitivity and 100% specificity was 5.7 mmol/L (103 mg/dL). **Conclusion:** Lowering the FPG criterion of IFG should have benefits in predicting new onset type 2 diabetes mellitus in Koreans. The economic and health benefits of applying the new IFG criteria should be evaluated in future studies.

Key Words: Impaired fasting glucose, normal glucose tolerance, type 2 diabetes mellitus

INTRODUCTION

In 1997, the American Diabetes Association (ADA) first introduced a category of impaired fasting glucose (IFG) that included a fasting plasma glucose (FPG) level between 6.1 and < 7.0 mmol/L (≥ 110 and < 126 mg/dL).[1] The World Health Organization adopted this new criterion in 1999.[2] The main reason for the new criteria was to create a fasting category that would be analogous to impaired glucose tolerance (IGT) based on the 75-g post-load glucose levels. In 2003, the ADA recommended that the threshold for diagnosing IFG should be lowered to 5.6 mmol/L or 100 mg/dL.[3] This was justified by the desire to identify similar proportions of the population with IFG and IGT and to produce an equivalent predictive power for progression to diabetes from the IGT and IFG categories. Data from the Pima Indians showed that the risk of diabetes increased markedly at an FPG concentration of higher than 5.6 mmol/L.[4] However, there has been debate over the advantages and the cost-benefit of this change.[5-7]

The lowering of the criteria for IFG from 6.1 mmol/L to 5.6 mmol/L increased the prevalence of IFG two to fivefold in most populations,[6-9] which could have a significant impact on the individuals as well as the healthcare system. The category of IFG is defined as the metabolic stage that is intermediate between the upper limit of normal FPG and the lower limit of diabetic FPG. IFG is not a clinical disease entity but rather a risk factor for the development of future diabetes.[10] Therefore, it is important to optimize the IFG

criteria. In reality, optimization requires conside-
ration of the costs of predicting or not predicting
a diagnosis of diabetes when diabetes does or
does not ultimately develop. There also may be an
ethnic difference in the criteria for IFG. Unlike
type 2 diabetic patients in western countries, most
Korean type 2 diabetic patients are not obese and
insulin deficiency, rather than insulin resistance, is
suggested to be the major pathogenic mecha-
nism.[11,12] We evaluated the prevalence of IFG
according to the old and new IFG criteria and the
prevalence of normal glucose tolerance (NGT),
IFG or diabetes after 2 years according to the
baseline FPG level. We examined whether lowering
the IFG criteria is appropriate in a Korean
population.

MATERIALS AND METHODS

Subjects

Among the subjects who underwent a medical
examination from January, 2002 to December,
2002 at Inha University Hospital, 7,510 subjects
underwent a follow up medical examination 2
years later in 2004. Twenty subjects were excluded
due to diagnosis of malignancy prior to the study
endpoint in 2004. A total of 279 subjects who were
diagnosed with diabetes before or during their
first examination in 2002 (223 subjects were newly
diagnosed at the examination in 2002 and 56
subjects were diagnosed with diabetes before the
health examination in 2002) were also excluded.
Finally, 7,211 subjects (6,224 men and 987 women)
who had either NGT or IFG were included in this
study. This study was approved by the Institu-
tional Review Board at Inha University Hospital.

Methods

The height, weight, blood pressure, FPG and
total cholesterol were measured at baseline and
after 2 years. The height and weight were
measured to the nearest 0.1 cm and 0.1 kg, while
the subjects were allowed to wear light clothing
and no shoes. Body mass index was calculated as
weight (kg) divided by the square of height (m).
Blood pressure was measured using an automatic

sphygmomanometer after the subject had been
seated for at least five minutes. Blood samples
were collected after overnight fasting. The fasting
glucose was measured by the glucose oxidase
method. Serum total cholesterol was measured
using an auto analyzer by the enzymatic colori-
metric method. The frequency of exercise was
determined for all subjects.

Diabetes was defined as a FPG value ≥ 7.0
mmol/L (126 mg/dL) or a prior diagnosis of
diabetes according to the ADA criteria.[3] IFG was
defined as a FPG value of 5.6 - 7.0 mmol/L (100 -
125 mg/dL) in the absence of a previous diagnosis
of diabetes according to the new ADA criteria.[3]
Old IFG was defined as a FPG value of 6.1 - 7.0
mmol/L (110 - 125 mg/dL) in the absence of a
previous diagnosis of diabetes in accordance with
the old ADA criteria.[1] Newly included IFG was
defined as a FPG value of 5.6 - 6.0 mmol/L (100 -
109 mg/dL) in the absence of a previous diagnosis
of diabetes.

Statistical analysis

Statistical analyses were performed using SPSS
software (version 11.0; SPSS Inc, Chicago, IL,
USA) and MedCalc software (version 8.2, MedCalc
Software, Belgium). All continuous variables
were expressed as mean ± standard deviation.
Comparisons of clinical characteristics between
baseline and follow up were performed by the
paired t-test. Comparisons of clinical charac-
teristics at baseline between groups were
performed by independent sample t-test or the
chi-square test. Subjects were divided into 8
groups according to the baseline FPG. The
percentage of NGT subjects at follow up was
calculated as the total number of NGT subjects
divided by the number of subjects in each group
based on the baseline FPG concentration and
multiplied by 100. The percentage of subjects
with IFG and diabetes at the 2004 evaluation
were also calculated by similar methods. A
receiver operating characteristic (ROC) curve for
predicting the future onset of diabetes after 2
years follow up was derived by plotting the
sensitivity vs 1-specificity for the baseline FPG of
less than 126 mg/dL. The optimal cutoff point
was defined as the point on the ROC curve

closest to the point at a 1-specificity of 0 and a sensitivity of 100%. A 2-sided value of *p* less than 0.05 was considered to be statistically significant.

RESULTS

Clinical characteristics of subjects

The mean age of the subjects was 38.8 ± 9.1 years. Clinical characteristics at baseline and after the 2 years follow up period are shown in Table 1. Among 7,211 subjects, 5,382 subjects were NGT and 1,829 subjects were IFG at baseline. Among 1,829 IFG subjects, 494 subjects were included in the old IFG group and 1,335 subjects in the newly included IFG group. Among the 5,382 NGT subjects, 4,483 (83.3%) subjects remained NGT, 878 (16.3%) subjects developed IFG and 21 (0.4%) developed diabetes after 2 years. Among 1,829 IFG subjects, 908 (49.6%) subjects returned to NGT, 851 (46.5%) remained to have IFG, and 70 (3.8%) developed diabetes after two years. Among the newly included 1,335 IFG subjects, 747 (56%) subjects returned to NGT, 566 (42.4%) remained IFG, and 22 (1.6%) developed diabetes. Among the 494 old IFG subjects, 161 (32.6%) returned to NGT, 285 (57.7%) remained IFG and 48 (9.7%) developed diabetes. Subjects who developed diabetes during the 2 years period had significantly older age, higher BMI, systolic and diastolic blood pressure, fasting plasma glucose, total cholesterol, alanine aminotransferase (ALT), and gamma-glutamyl transpeptidase (gamma-GT) levels (Table 2).

Table 1. Clinical Characteristics of Subjects (n = 7211) at Baseline and After 2 Years Follow-up

	Baseline	After 2 years	*p* value
Weight (kg)	67.4 ± 10.4	67.9 ± 10.6	< 0.001
BMI (kg/m^2)	23.7 ± 2.9	23.9 ± 2.9	< 0.001
Glucose (mmol/L)	5.15 ± 0.61	5.22 ± 0.65	< 0.001
Total cholesterol (mmol/L)	4.88 ± 0.87	4.92 ± 0.86	< 0.001
Systolic BP (mmHg)	125.0 ± 14.8	129.4 ± 15.4	< 0.001
Diastolic BP (mmHg)	78.2 ± 11.1	77.5 ± 10.8	< 0.001
Frequency of exercise (/wk)	1.36 ± 1.68	1.59 ± 1.71	< 0.001

BMI, body mass index; BP, blood pressure.
Data are expressed as means ± SD.

Table 2. Baseline Characteristics of Non-Diabetic and New-Diabetic Subjects at 2 Years Follow-up

	Non-diabetic	Diabetic	*p* value
n (M/F)	7120 (6139/981)	91 (85/6)	0.05
Age (yrs)	38.7 ± 9.1	43.4 ± 9.4	< 0.001
BMI (kg/m^2)	23.7 ± 2.9	25.6 ± 3.7	< 0.001
Systolic BP (mmHg)	124.9 ± 14.7	133.8 ± 19.3	< 0.001
Diastolic BP (mmHg)	78.2 ± 11.0	83.8 ± 13.6	< 0.001
Fasting glucose (mmol/L)	5.14 ± 0.60	6.01 ± 0.70	< 0.001
Total cholesterol (mmol/L)	4.88 ± 0.87	5.10 ± 1.00	0.02
ALT (IU/L)	32.3 ± 33.2	55.5 ± 37.2	< 0.001
gamma-GT (IU/L)	39.3 ± 38.3	73.6 ± 367.6	< 0.001
Frequency of exercise (/wk)	1.4 ± 1.7	1.4 ± 1.8	0.62
Family history of diabetes (%)	5.4	13.2	0.001

M, male; F, female; BMI, body mass index; BP, blood pressure.
Data are expressed as means ± SD.

Percentage of NGT, IFG, and newly developed diabetes at follow up according to the fasting glucose concentration at baseline

The percentage of NGT subjects at follow up decreased with an increase in the FPG concentration at baseline. The percentage of IFG subjects and newly developed diabetic subjects at follow up increased with the increase of FPG concentration at baseline (Fig. 1).

Comparison of the new and old diagnostic criteria of IFG

Subjects in the old IFG group had significantly older age, higher BMI, total cholesterol, and systolic and diastolic blood pressure compared with those in the newly included IFG group (Table 3). In correctly predicting incident diabetes in the 2 years follow-up period, the old criteria had a sensitivity of 53%, specificity of 93.7%, positive predictive value of 9.7%, and negative

predictive value of 99.4%. Applying the new diagnostic criteria, the sensitivity was 76.9%, specificity was 75.3%, positive predictive value was 3.8%, and the negative predictive value was 99.6%. After applying the new IFG criteria the specificity showed an 18.4% decrease whereas the sensitivity showed a 23.9% increase compared to the old IFG criteria. Using the ROC curve, the cutoff point that maximizes the sum of the sensitivity and specificity can be used to discriminate between the groups of subjects who have a high risk of developing diabetes after 2 years. The baseline FPG level at the point on the ROC curve that was closest to the ideal of 100% sensitivity and 100% specificity was 103 mg/dL (5.7 mmol/L). The sensitivity and specificity of 103 mg/dL were 70.3% and 85.4%, respectively.

DISCUSSION

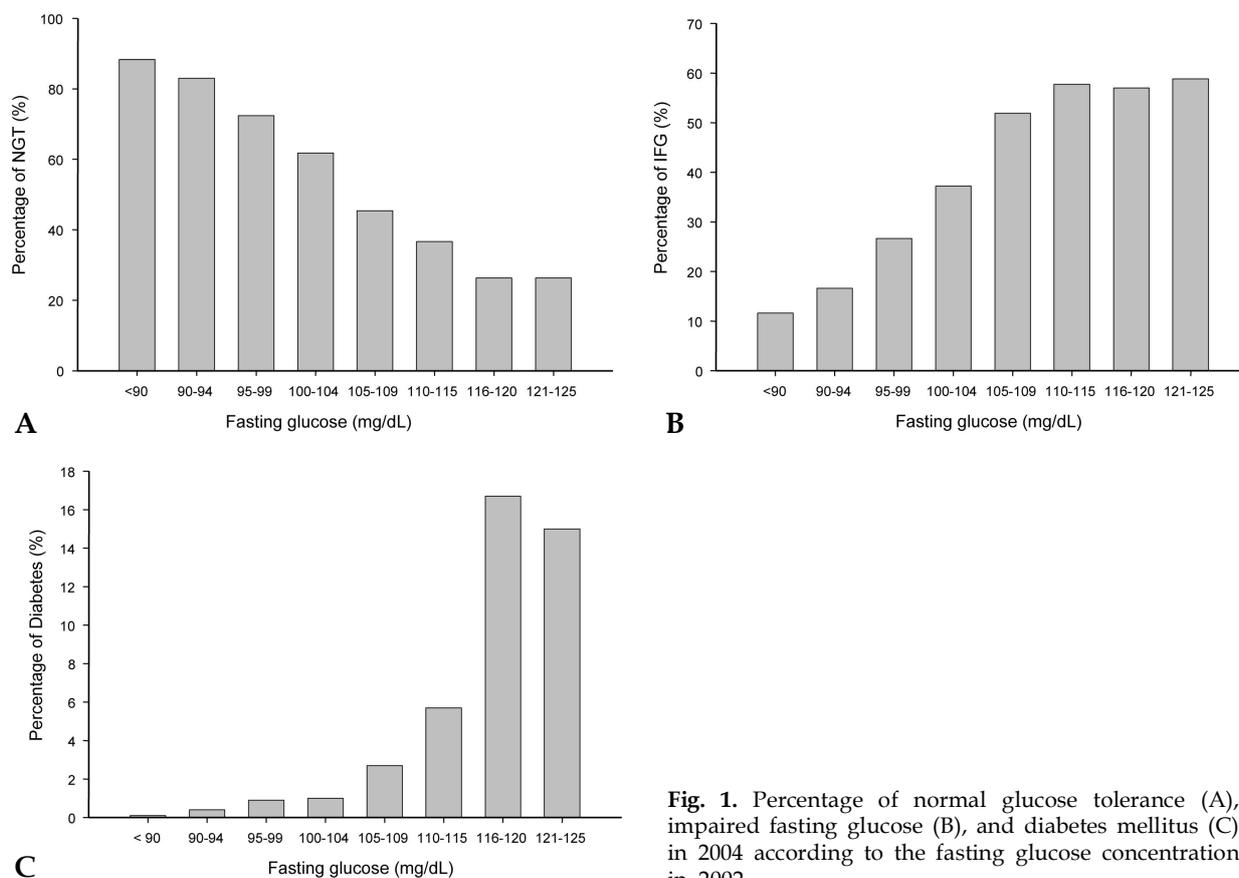The IFG category was introduced to designate

Fig. 1. Percentage of normal glucose tolerance (A), impaired fasting glucose (B), and diabetes mellitus (C) in 2004 according to the fasting glucose concentration in 2002.

Table 3. Comparison of Clinical Characteristics Among Subjects at Baseline Between the Old IFG Group and the Newly Included IFG Group

	Newly included IFG group	Old IFG group	*p* value
Subjects (n)	1335	494	
Age (yrs)	40.9 ± 9.0	43.2 ± 8.8	< 0.001
Female (%)	7.3	4.7	0.04
Weight (kg)	69.4 ± 9.9	70.3 ± 10.4	0.10
BMI (kg/m^2)	24.2 ± 2.8	24.7 ± 3.0	0.002
Glucose (mmol/L)	5.75 ± 0.15	6.39 ± 0.24	< 0.001
Total cholesterol (mmol/L)	5.02 ± 0.89	5.13 ± 0.89	0.02
Systolic BP (mmHg)	128.1 ± 14.4	132.3 ± 16.5	< 0.001
Diastolic BP (mmHg)	80.1 ± 11.0	83.0 ± 12.3	< 0.001
Frequency of exercise (/wk)	1.40 ± 1.68	1.45 ± 1.64	0.51
Family history of diabetes (%)	9.3	7.6	0.25

BMI, body mass index; BP, blood pressure.
Data are expressed as means ± SD.
Old IFG was defined as a fasting plasma glucose value of 6.1 - 7.0 mmol/L (110 - 125 mg/dL) in the absence of previous diagnosis of diabetes. Newly included diabetes was as a fasting plasma glucose value of 5.6 - 6.0 mmol/L (100 - 109 mg/dL) in the absence of previous diagnosis of diabetes.

the zone between the upper limit of normal FPG and the lower limit of diabetic FPG. IFG represents an intermediate state of abnormal glucose regulation and is a risk factor for future development of diabetes. In 2003, the ADA recommended that the lower limit for the diagnosis of IFG should be changed from 6.1 to 5.6 mmol/L.[3] Type 2 diabetes is an epidemic, and the public health burden of the disease remains enormous. The magnitude of the epidemic, coupled with complex treatment requirements that are difficult and costly to implement, makes the prevention of diabetes a critical public health goal.[13] People in Asia develop diabetes at a lower degree of obesity and at younger ages, suffer longer from chronic diabetic complications, and die sooner than those in developed countries.[14] Therefore, it is important and necessary to evaluate the proper threshold for the diagnosis of IFG in Koreans.

In this study, lowering the FPG criterion for IFG from 6.1 to 5.6 mmol/L resulted in an increase of prevalence of IFG from 6.9% to 25.3%. Lowering the diagnostic threshold for IFG has increased the prevalence of IFG two to fivefold in most populations,[6-9] which is consistent with the findings of this study. Many people revert to normoglycaemia on subsequent testing after a first test showing

raised glucose levels, and there is no fixed state of pre-diabetes. In this study, 49.6% of patients from the IFG group reverted to NGT on subsequent testing, 56% from the newly included IFG group and 32.6% from the old IFG group.

This study demonstrated that the incidence rates of diabetes during 2 years for IFG categories of 5.6 - 6.0 and 6.1 - 7.0 mmol/L were 1.6% and 9.7%, respectively. Lowering the FPG criteria for IFG included more subjects who were younger, had lower BMI, total cholesterol, and systolic and diastolic blood pressure. The new diagnostic criteria increased the sensitivity of predicting incident diabetes after 2 years from 53% to 76.9% compared to the old criteria. On the other hand, the new criteria resulted in a decrease in specificity from 93.7% to 76.9%. Using the ROC curve, the cutoff point that maximizes the sum of sensitivity and specificity was 5.7 mmol/L (103 mg/dL), which is much lower than the cutoff value of the old IFG criteria. The transition from impaired fasting glucose to diabetes may take many years, and current estimates indicate that most individuals with pre-diabetic states eventually develop diabetes.[15-20] Therefore, considering the short follow up period of 2 years in this study, the lowering of the FPG threshold level in diagnosing IFG

seems to be needed to properly identify subjects who have risk of developing diabetes in Koreans. A previous study on Korean subjects in a rural area showed that the mean baseline FPG of subjects who developed incident diabetes after 6 years follow up was 5.4 - 5.6 mmol/L.[21] The mean FPG of subjects developing incident diabetes was lower than that seen in our study which was 6.0 mmol/L. The difference in the FPG levels in those who develop diabetes in these 2 studies seems to be mainly due to the different follow up period.

The result of this study is similar to that seen in other populations. The FPG value at the point on the ROC curve closest to the ideal 100% sensitivity and 100% specificity over the glycemic range of 4.5 - 7.0 mmol/L to predict diabetes was 5.7 mmol/L in a Dutch population, 5.6 mmol/L in a Pima Indian population, 5.4 mmol/L in a Mauritius population, and 5.2 mmol/L in a San Antonio population.[3,4,22,23] These values suggest that 6.1 mmol/L was inappropriately high as a lower limit for IFG. Thus, changing the IFG cut point to 5.6 mmol/L would optimize its sensitivity and specificity for predicting future diabetes.[3] Further studies on the total benefit or cost to an individual who is diagnosed with IFG by the new criterion, compared to the old IFG criterion, are needed to evaluate the effect of the change of the diagnostic criteria on our health system. Based on the NHANES III data, about 89% of 25- to 75-yr-olds with an FPG of 100 - 109 mg/dL have another indication (high BMI, hypertension, or dyslipidemia) for diet and exercise, and therefore, could be identified and treated without being labeled as having IFG. Thus, of all patients newly labeled as "IFG", only 11% have no other indication for diet and exercise recommendations.[7] Since little is known about the socioeconomic benefit of lowering the IFG cutoff point, these outcomes should be evaluated to be truly sure that the new IFG criteria will be beneficial.

There are several limitations in the present study. First, the diagnosis of diabetes was based on a single measurement of FPG. Although the oral glucose tolerance test (OGTT) is recognized as a valid way to diagnose diabetes, use of the test for diagnostic purposes in clinical practice has been discouraged for several reasons (e.g., incon-

venience, less reproducibility, great cost). The measurement of FPG is less expensive and less intrusive than the 2-h PG. Commonly, in clinical practice, risk prediction will occur using only the fasting level without knowledge of the 2-h value. The ADA expert committee encourages the use of fasting glucose rather than the OGTT for the diagnosis of diabetes and other categories of glucose regulation in clinical and epidemiological studies.[1] Second, since no OGTTs were conducted, the prevalence of diabetes could have been underestimated. In a study of elderly Koreans, the prevalence of newly diagnosed diabetes was found to be higher according to the World Health Organization (WHO) criteria using OGTTs than by the ADA criteria using fasting glucose alone.[24]

In conclusion, the lowering of the IFG criteria from 6.1 mmol/L (110 mg/dL) to 5.6 mmol/L (100 mg/dL) increased the prevalence of IFG from 6.6% to 24.4%. The optimal cutoff for the baseline FPG that predicts incident diabetes after 2 years was 5.7 mmol/L (103 mg/dL). The lowering of the IFG threshold to 5.6 mmol/L should have benefit over the old threshold (6.1 mmol/L) since it could optimize sensitivity and specificity for predicting the future onset of diabetes in the Korean population.

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