

Reversion From Type 2 Diabetes to Nondiabetic Status

Influence of the 1997 American Diabetes Association criteria

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OBJECTIVE — To determine the incidence and the rate of reversion of type 2 diabetes to a nondiabetic status in the 7- to 8-year follow-up of the San Antonio Heart Study, and to determine the influence of the recent 1997 American Diabetes Association (ADA) criteria for diabetes on these rates. Individuals who revert have been problematic for those developing criteria for the diagnosis of type 2 diabetes. Few studies have addressed this issue using 1979 National Diabetes Data Group/1980 World Health Organization (WHO) criteria.

RESEARCH DESIGN AND METHODS — We studied 3,682 Mexican-American and non-Hispanic white men and nonpregnant women who completed both the baseline and follow-up examination of the San Antonio Heart Study. Incidence and reversion rates were calculated using both the 1980 WHO and the 1997 ADA criteria. Risk factors for reversion were identified, and the best fitting model using multiple logistic regression was determined using both the 1980 WHO and the 1997 ADA criteria.

RESULTS — Using the 1997 ADA criteria, the age-adjusted incidences of type 2 diabetes for Mexican-American men and women were 10.8 and 12.2%, respectively. For non-Hispanic white men and women, the age-adjusted incidence rates were 5.5 and 5.1%, respectively. Similar age-adjusted incidences were recorded using the 1980 WHO criteria. The reversion rate for individuals with type 2 diabetes was 11.5% using the 1980 WHO criteria and 12.5% using the 1997 ADA criteria. These rates were not significantly different. Numerous risk factors for reversion were identified. The best fitting model, after controlling for age, sex, and ethnicity, included baseline 2-h glucose level, baseline HDL cholesterol, and previous diagnosis of diabetes. The models were the same for both the 1980 WHO and the 1997 ADA criteria.

CONCLUSIONS — There was no significant difference in the incidence or the reversion rates for diabetic subjects using either 1980 WHO or 1997 ADA criteria. In addition, the risk factors for reversion were very similar using either set of criteria. The revision of the ADA criteria did not have a significant influence on reversion in this study.

Individuals with type 2 diabetes who later revert to nondiabetic status have been problematic for those developing criteria for diagnosis of this disease. A high reversion rate might indicate that criteria are too sensitive, i.e., labeling as diabetic individuals who did not, in fact, have diabetes. However, few studies have been conducted

examining individuals who revert. The American Diabetes Association (ADA) has recently recommended revisions to the 1979 National Diabetes Data Group (NDDG)/1980 World Health Organization (WHO) criteria for diagnosis of diabetes (1). The cut point for a positive fasting glucose was lowered from 140 to 126 mg/dl to

better correspond to the cut point used with the oral glucose tolerance test (OGTT) (200 mg/dl 2 h after an oral glucose load), which remained unchanged. It has been shown that a fasting glucose level of 140 mg/dl is less sensitive than a 2-h glucose level of 200 mg/dl (2). In addition, the lowering of the fasting criteria may lessen the necessity for using the OGTT in large epidemiological studies, since the new fasting cut point should identify a proportion of the population similar to that identified by the 2-h cut point.

Before the establishment of the 1979 NDDG (3) and 1980 WHO (4) criteria, approximately one-third of individuals diagnosed with so-called “chemical” or “borderline” diabetes typically reverted to a nondiabetic status (3), a misclassification rate considered unacceptable. With the establishment of the 1980 WHO criteria, which raised the fasting and 2-h cut points, the reversion rate was substantially reduced. For example, in the San Antonio Heart Study, which had a single follow-up at 7–8 years, the reversion rate was only 14% (5). The purpose of the present study is to determine what effects the 1997 ADA criteria will have on reversion rates. Specifically, will there be a significant increase in the reversion to nondiabetic status because of the lowering of the fasting cut point? A second objective is to examine factors associated with reversion. And lastly, the effect on the incidence and reversion of diabetes of not using the OGTT was also assessed.

RESEARCH DESIGN AND

METHODS — The San Antonio Heart Study is a population-based study of diabetes and cardiovascular disease risk factors in Mexican Americans and non-Hispanic whites. The study initially enrolled 3,301 Mexican-American and 1,857 non-Hispanic white men and nonpregnant women in two phases between 1979 and 1988. The participants were 25–64 years of age at enrollment and were randomly selected from low-, middle-, and high-income neighborhoods in San Antonio. The first phase of an 8-year follow-up began in October 1987 to examine the incidence of type

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Received for publication 17 December 1997 and accepted in revised form 28 April 1998.

Abbreviations: ADA, American Diabetes Association; NDDG, National Diabetes Data Group; OGTT, oral glucose tolerance test; WHO, World Health Organization.

Table 1—A 7- to 8-year incidence (%) of diabetes by WHO and ADA criteria stratified by age for male and female subjects

	Male subjects						Female subjects					
	Mexican-American			Non-Hispanic white			Mexican-American			Non-Hispanic white		
	n	WHO	ADA	n	WHO	ADA	n	WHO	ADA	n	WHO	ADA
Age (years)												
25-34	232	4.3	4.7	128	3.9	3.9	313	5.8	7.0	151	2.6	2.6
35-44	242	7.0	7.5	141	4.3	4.3	366	9.8	9.6	199	4.5	5.1
45-54	213	10.3	11.4	151	6.6	6.6	294	14.3	15.6	166	7.2	7.2
55-64	144	23.6	23.2	127	7.1	8.0	195	19.0	18.6	166	4.2	5.5
Age-adjusted*	—	10.4	10.8	—	5.3	5.5	—	11.7	12.2	—	4.6	5.1

*Adjusted by direct method (from Lilienfeld and Lilienfeld [18]).

2 diabetes and cardiovascular disease. The follow-up of the first phase was completed in November 1990. In October 1991, a similar 7-year follow-up began for phase two of the study, which was completed in the fall of 1996. A total of 3,682 individuals were seen at the two follow-ups (71.4%).

Descriptions of the survey procedures used at the baseline and follow-up examinations have been published previously (6-8). Plasma glucose was determined after a 12-h fast and 2 h after a standard oral glucose load. Fasting serum lipid, lipoprotein, and insulin concentrations, along with blood pressure, height, weight, and subscapular and triceps skinfolds, were measured at baseline and follow-up as previously described (9,10). BMI was calculated as weight (kilograms) divided by height (meters) squared. Obesity was defined as a BMI ≥ 27 kg/m². Socioeconomic status was assessed at baseline using the Duncan Socioeconomic Index (11,12). Chronic disease at baseline was defined as self-reported heart attack, cancer, gallbladder disease, or stroke or a positive Rose angina questionnaire. Ethnicity was determined using a previously published algorithm that considers parental surnames and birthplaces, stated ethnicity of grandparents, and participant's preferred ethnic identity when indicating a distinct national origin (13).

Subjects were considered to have type 2 diabetes if they met either the 1980 WHO (4) or the 1997 ADA (1) plasma glucose criteria. Subjects who gave a history of diabetes and who were under treatment with either insulin or oral antidiabetic agents were also considered to have diabetes regardless of their plasma glucose levels. Thus, even those who responded well to diabetic medication would still be classified as having diabetes at follow-up if they remained on medication. Subjects with diabetes not taking insulin were considered to have type 2 diabetes.

Those taking insulin were considered to have type 2 diabetes if they had a BMI > 27 kg/m² and age of onset > 30 years. Reversion rates based on the two diagnostic criteria were calculated by dividing the number of participants who met each criterion for type 2 diabetes at baseline but did not meet that criterion at follow-up by the total number of participants who met the corresponding criterion for diabetes at baseline.

Statistical analysis was performed using SAS statistical software (14). Odds ratios were calculated using logistic regression. χ^2 and *t* tests were used to determine statistical differences in proportions and means, respectively. The criterion for both entering and retention in the logistic regression model was 0.05.

RESULTS — The 7- to 8-year incidence of type 2 diabetes was similar using either the 1980 WHO or the 1997 ADA criteria. The crude incidence was 8.63% (280/3,242) using the 1980 WHO criteria, compared with 9.08% (293/3,226) using the 1997 ADA criteria. There was no significant difference in incidence rates between the criteria when the study population was stratified by age, ethnic group, and sex (Table 1).

Table 2 presents the percentage of diabetic subjects who would have been missed if the 2-h glucose criteria had not been used (i.e., had been ignored, as would be the case in a study that measured fasting

glucose only). These individuals did not meet fasting glucose criteria, were not on diabetic medication, and did not have a previous diagnosis of diabetes. Thus, they were diagnosed solely on the basis of their 2-h glucose level. Using the 1980 WHO criteria, 33.4% of diabetic subjects would have been missed if only the fasting glucose had been available. The referent group for this percentage is diabetic subjects diagnosed on the basis of a fasting or a 2-h value, both of which exceeded the WHO diagnostic cut points. This percentage was higher (although not significantly) than the 27.3% that would have been missed using the 1997 ADA criteria. At follow-up, using the 1980 WHO criteria, 27.8% of diabetic subjects would have been missed had the 2-h value not been available, compared with 21.0% using the 1997 ADA criteria. This difference was statistically significant.

The rate of reversion from type 2 diabetes at baseline to a nondiabetic status at follow-up was 11.5% (35/304) using the 1980 WHO criteria and 12.5% (40/320) using the 1997 ADA criteria (the denominator for reversion rates was all diabetic subjects diagnosed according to the criterion in question). These rates were not significantly different. The baseline characteristics of participants who reverted from type 2 diabetes to a nondiabetic status versus those who remained diabetic at follow-up are presented in Table 3. There was little difference between the 1980 WHO and

Table 2—Percentage of diabetic subjects who would have been missed if 2-h glucose criteria (≥ 200 mg/dl) had not been used

	Baseline	Follow-up
1980 WHO criteria*	33.4 (107/320)	27.8 (155/557)
1997 ADA criteria†	27.3 (92/337)	21.0‡ (122/582)

*Fasting glucose ≥ 140 mg/dl; †fasting glucose ≥ 126 mg/dl; ‡*P* < 0.01 (WHO vs. ADA).

Table 3—Baseline characteristics of participants who did and did not revert to nondiabetic (ND) status based on WHO versus ADA criteria

	1980 WHO criteria			1997 ADA criteria		
	Revert to ND	Remain type 2 diabetic	P value	Revert to ND	Remain type 2 diabetic	P value
n	35	269		40	280	—
Sex (% male)	37.1	41.3	0.641	42.5	42.1	0.966
Age (years)	53.3	52.2	0.483	52.8	52.0	0.582
Ethnicity (% Mexican American)	45.7	84.8	0.001	52.5	73.1	0.001
Age at onset of diabetes (years)	51.7	48.3	0.058	51.8	48.2	0.038
Duncan score	50.4	41.9	0.032	48.9	41.6	0.048
Years of education	11.4	10.0	0.161	11.0	10.1	0.361
BMI (kg/m ²)	28.0	31.7	0.001	27.9	31.7	0.000
Change in BMI (kg/m ²)	0.365	−0.758	0.002	0.160	−0.768	0.009
Weight change (lb)	0.30	−5.74	0.006	−0.84	−5.82	0.023
Systolic blood pressure (mmHg)	125.1	126.1	0.701	125.6	126.0	0.881
Diastolic blood pressure (mmHg)	73.6	74.3	0.645	74.6	74.5	0.970
Triglycerides (mg/dl)	163.6	212.0	0.007	163.2	222.6	0.002
HDL cholesterol (mg/dl)	57.3	44.5	0.000	55.8	44.3	0.000
Fasting glucose (mg/dl)	123.3	159.7	0.001	124.7	158.5	0.000
2-h glucose (mg/dl)	219.2	293.5	0.000	210.4	290.6	0.000
Fasting insulin (μU/ml)	19.9	27.2	0.189	20.0	27.4	0.217
Duration of type 2 diabetes (years)	0.63	4.36	0.000	0.59	4.29	0.000
Diabetic medication (%)	8.6	36.9	0.001	7.5	35.6	0.001
Met 2-h criteria only (%)	68.6	29.7	0.001	55.0	23.9	0.001
Met 1997 ADA criteria only (%)	—	—	—	15.0	3.6	0.002
Newly diagnosed (%)	88.6	47.4	0.001	90.0	48.9	0.001

1997 ADA criteria. Participants who reverted were more likely to be Caucasian, had an older age of diabetes onset, were of higher socioeconomic status, and had a significantly lower BMI. Those who reverted gained weight and increased their BMI from baseline to follow-up, while those who remained diabetic lost weight and reduced their BMI. Mean triglycerides, fasting and 2-h glucose levels, fasting insulin, and duration of diabetes were all significantly higher in those who remained diabetic, while HDL cholesterol was significantly lower. Those who reverted were much less likely to be on diabetic medication at baseline compared with those who remained diabetic.

Individuals who reverted were much more likely to be diagnosed solely on the basis of their 2-h OGTT, compared with those who remained diabetic (Table 3). This was true using either the 1980 WHO or the 1997 ADA criteria. A total of 16 additional diabetic subjects were diagnosed based on the 1997 ADA criteria who would not have been diagnosed had the 1980 WHO criteria been used. Those who reverted were more likely to have met the new criteria only compared with those who remained diabetic.

In this study 52.8% of diabetic subjects (by the 1997 ADA criteria) were newly

diagnosed at the baseline survey. We assume that individuals not previously diagnosed, in general, have less severe diabetes and have fewer clinical symptoms than those who had been diagnosed previously. Thus, it would be expected that the newly diagnosed diabetic subjects would have a higher reversion rate. As presented in Table 3, individuals who reverted were much more likely to have been newly diagnosed compared with those who remained diabetic.

Table 4 presents factors predictive of reversion. The factors that were significant were similar regardless of the criteria used. Elevated HDL cholesterol, higher socioeco-

nomics status, newly diagnosed at baseline, meeting 2-h OGTT criteria only, and meeting the 1997 ADA criteria only were all significantly predictive of reversion. Weight gain and older age of onset did not quite reach statistical significance.

Table 5 presents the baseline factors that are inversely predictive of reversion, i.e., they are predictive of remaining diabetic. Again, the factors were similar regardless of diabetes criteria. Mexican-American ethnicity, obesity, presence of a chronic disease, use of diabetic medication, elevated BMI, elevated fasting glucose, elevated 2-h glucose, elevated triglycerides, longer dura-

Table 4—Factors at baseline predictive of reversion

	1980 WHO criteria	1997 ADA criteria
Weight change (5 lb)	1.09 (0.079)	1.08 (0.123)
HDL cholesterol (5 mg/dl)	1.30 (0.000)	1.27 (0.000)
Socioeconomic status (Duncan's scale, 10 U)*	1.20 (0.034)	1.17 (0.050)
Age at onset (10-year intervals)	1.44 (0.074)	1.48 (0.049)
Newly diagnosed at baseline	8.60 (0.000)	9.40 (0.000)
Met 2-h criteria only	4.73 (0.000)	3.70 (0.000)
Met new ADA criteria only	—	4.76 (0.004)

Data are odds ratio (P). *Scale 1–100.

Table 5—Factors at baseline predictive of remaining diabetic

	1980 WHO criteria	1997 ADA criteria
Ethnicity (Mexican-American versus Caucasian)	6.62 (0.000)	4.61 (0.000)
Obesity (BMI ≥ 27 kg/m ²) at baseline	4.20 (0.000)	3.86 (0.000)
Chronic disease at baseline	3.00 (0.018)	2.82 (0.017)
Diabetic medication at baseline	6.25 (0.003)	6.80 (0.002)
BMI at baseline (5 kg/m ²)	1.92 (0.001)	1.96 (0.000)
Fasting glucose at baseline (10 mg/dl)	1.16 (0.002)	1.16 (0.001)
Triglycerides at baseline (10 mg/dl)	1.05 (0.037)	1.05 (0.019)
Diabetes duration at baseline (years)	1.30 (0.012)	1.31 (0.010)
2-h glucose at baseline (10 mg/dl)	1.18 (0.000)	1.18 (0.000)
Neighborhood		
Low income versus high income	3.58 (0.006)	3.30 (0.005)
Medium income versus high income	1.25 (0.620)	1.54 (0.311)

Data are odds ratio (P).

tion of diabetes, and living in a low-income neighborhood were all significantly predictive of remaining diabetic.

Table 6 presents the best fitting logistic regression models for prediction of reversion. Sex, ethnicity, and age were all forced into the models. The factors that entered the model, which were identical for either set of diabetes criteria, were elevated 2-h glucose level, decreased HDL cholesterol, and previous diagnosis of diabetes.

For those with diabetes at baseline based on the 1997 ADA criteria, a study of baseline characteristics was conducted comparing those who returned with those who did not return. There were no significant differences between the returnees and non-returnees in sex, age, ethnicity, years of education, BMI, obesity, fasting insulin, cigarettes smoked per day, chronic disease at baseline, neighborhood, diabetic medication at baseline, or age at diagnosis. Only glucose level (lower in the returnees) and socioeconomic status (higher in the returnees) were significantly different between the returnees and nonreturnees. Both of these differences would tend to inflate the reversion rates. We therefore estimated the reversion probabilities for all individuals who were diabetic at baseline by entering their baseline characteristics into the best fitting logistic regression model (Table 6). The reversion probabilities were then cumulated to estimate the reversion rate for the entire diabetic population at baseline. These estimates were similar to the reversion rates based on only those who returned for follow-up. Using the 1997 ADA criteria, the estimated reversion rate was 10.9% for all diabetic subjects at baseline (compared with 11.5% for those who

returned for follow-up only). Using the 1980 WHO criteria, the estimated reversion rate was 11.5% (compared with 12.5% for those who returned for follow-up only).

CONCLUSIONS — An important argument for the revision of the ADA criteria was to achieve a better correspondence between the cut point for the fasting plasma glucose and the 200-mg/dl cut point for the 2-h glucose (1). The percentage of the population with a 2-h glucose >200 mg/dl is much higher than the percentage with a fasting glucose >140 mg/dl. By lowering the fasting cut point to 126 mg/dl, the hope was that the percentage of the population exceeding this lower fasting cut point would be similar to the percentage exceeding the 2-h cut point of 200 mg/dl. In our data, however, whereas 7.9% of the population had 2-h values >200 mg/dl, only 5.8% had fasting values >126 mg/dl. In our data, it would be necessary to lower the fasting cut point to 115 mg/dl to achieve the same percentage above the cut point (i.e., 7.9%) as exceeded the 2-h cut point of 200 mg/dl. Thus,

although our results confirm that the new ADA criteria reduced the number of diabetic subjects who would have been missed had the OGTT not been used (Table 2), there remained a significant discrepancy between the number of participants who exceeded the 2-h glucose criteria compared with those who exceeded the new ADA fasting criteria.

The change from the 1980 WHO criteria to the 1997 ADA criteria for type 2 diabetes did not significantly influence the incidence of diabetes or the rate of reversion to a nondiabetic status. The 7- to 8-year incidence increased nonsignificantly from 8.63 to 9.08%. The lack of a significant increase in incidence is not surprising, since the new fasting criteria continue to be less sensitive than the 2-h criteria. Therefore, most individuals who exceed the new fasting criteria should already have been positive for the 2-h glucose.

It is clear from the results of this study that the individuals who reverted to a nondiabetic status had less severe diabetes and fewer risk factors for diabetes. In general, their blood glucose levels, BMI, triglycerides, and fasting insulin at baseline were significantly lower than those who remained diabetic, while their socioeconomic status score and HDL cholesterol levels were significantly higher. In addition, those who reverted were more likely to be newly diagnosed and Caucasian and less likely to have been on diabetic medication at baseline.

One possible cause of reversion might be weight loss between baseline and follow-up. In our study, there was a significant difference in the BMI change from baseline to follow-up between those who reverted and those who remained diabetic. However, those who reverted actually gained weight, while those who remained diabetic lost weight. This is perhaps not as counterintuitive as it might seem, when it is realized that individuals with persistent disease

Table 6—Best model for prediction of reversion (with sex, age, and ethnicity forced into the model)

	1980 WHO criteria	1997 ADA criteria
Sex (female versus male)	1.00 (0.39–2.59)	0.90 (0.38–2.13)
Age (5 years)	1.05 (0.81–1.38)	1.10 (0.85–1.42)
Ethnicity (Caucasian versus Mexican-American)	5.37 (2.04–14.15)	3.19 (1.28–7.92)
2-h glucose (10 mg/dl)	0.88 (0.81–0.97)	0.87 (0.80–0.95)
HDL cholesterol (5 mg/dl)	1.28 (1.09–1.50)	1.25 (1.08–1.45)
Newly diagnosed	12.05 (2.84–51.13)	10.40 (2.64–41.95)

Data are odds ratio (95% CI).

tend to lose weight, while those without disease tend to gain weight with age. In any case, a reduction in weight did not account for reversion in this study.

Recent authors have questioned the usefulness of the OGTT (15,16), which is known to be poorly reproducible (17). It is often regarded as a cumbersome, time-consuming, and patient-unfriendly procedure (15), and it appears that many physicians do not routinely use it (16). The question arises that if the OGTT is no longer used, what effect will this have on the diagnosis of type 2 diabetes? Our results indicate that individuals diagnosed solely on the basis of an OGTT (who would not otherwise meet criteria for diabetes) were much more likely to revert to a nondiabetic status than were the other diabetic subjects. Even though ~21–27% of diabetic subjects would have been missed without the OGTT, 23.5% of those that would have been missed reverted and, therefore, may well have been misclassified in the first place.

One concern about lowering the criteria for a fasting glucose is that individuals who have more questionable cases may be labeled as diabetic. Our data indicate that individuals who are diagnosed solely on the basis of the new criteria were much more likely to revert compared with those who met only the old criteria. Thus, it appears that a less stable group of diabetic subjects is introduced with the lowering of the ADA fasting criteria. However, the inclusion of the new cases did not significantly increase the overall reversion rate of the diabetic subjects.

In conclusion, the lowering of the ADA criteria for a positive fasting glucose did not significantly increase the rate of reversion or the incidence of diabetes in this study. Individuals who reverted were likely to have had less severe diabetes. There were a number of significant predictors for rever-

sion. The final model, using logistic regression analysis with age, sex, and ethnicity forced in the model, consisted of 2-h glucose, HDL cholesterol, and a previous diagnosis of diabetes. The final model was the same for either the old or new ADA criteria.

Acknowledgments — This study was supported by grants from the National Heart, Lung and Blood Institute (RO1HL24799 and R37HL36820). J.P.B. was supported by an ADA Mentor-Based Post-Doctoral Fellowship Award.

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