Diabetes Mellitus After GDM

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The impact of factors that influence diabetes mellitus (DM) and impaired glucose tolerance (IGT) incidence rates among former gestational diabetes mellitus (GDM) patients undermine attempts at interstudy comparisons. The recommended diagnostic standards for GDM by oral glucose tolerance test (OGTT) are the O'Sullivan and Mahan criteria and the World Health Organization (WHO) criteria for IGT, which result in prevalence rates of 2.5 and 7.2%, respectively, when applied to 752 unselected pregnant women. In applying the O'Sullivan and Mahan criteria, the current open-ended definition of GDM without rules either to exclude overt diabetes uncovered by pregnancy or to require a return to a normal OGTT after pregnancy is shown to be a major source of differences in subsequent incidence rates of diabetes. For subsequent nonpregnant diagnoses, the differences between WHO and National Diabetes Data Group criteria and the allowable modifications within each of the diagnostic standards all result in different incidence rates of diabetes. Review of 12 worldwide studies of diabetes among former GDM patients indicated a wide range of incidence rates, from 19 to 87% for combined DM and IGT and 6 to 62% for DM. In applying WHO DM criteria to GDM patients and control subjects, the excess risk of diabetes among GDM patients was 18% in Copenhagen and 30.9% in Boston, MA. The potential impact of varying observation periods within studies was seen when the application of an actuarial method added a further 50% to the Boston incidence rates of both GDM patients and control subjects. Although the variability in diabetes incidence rates is wide, there is broad general agreement on the predictive nature of gestational blood glucose levels. *Diabetes* 40 (Suppl. 2):131–35, 1991

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Geographic similarities and contrasts in follow-up glucose tolerance tests among former gestational diabetes mellitus (GDM) patients are the subject of this assessment. Each study of this topic requires a baseline count of GDM patients and, subsequently, a count of the subset that goes on to diabetes mellitus—a deceptively simple task. However, deciding who to count determines the outcome of the investigation, thus focusing attention on the critical role of diagnostic standards. Agreeing on clinically relevant diagnostic standards has proved difficult due to the paucity of outcome data and has been further complicated by the fact that the early stages of this disorder have many of the characteristics of a chronic remittent disease. The fluctuations in the course of both GDM and non-insulin-dependent diabetes mellitus (NIDDM) attest to this characterization. Because data from studies on GDM in Boston, MA, indicate that having GDM in one pregnancy and not in a subsequent one (1) and exhibiting GDM in one trimester and not in the next (2) does not, for the most part, alter the incidence rates for diabetes mellitus on follow-up, the remittent characteristics can be set aside for the purposes of this review.

The initial focus of this report is appraisal of some fundamental factors that influence the enumeration of both GDM and diabetic patients. Important considerations, such as the characteristics of the study population and its risk factor composition, will be bypassed, not to minimize them but because a decision on who to count must come before the analyses of factors that modify the interpretation of the count. Finally, I present a summary of the literature on follow-up studies of GDM.

Herein, I briefly review the following topics: *1*) diagnostic standards for GDM, *2*) choice of diagnostic criteria for diabetes mellitus, *3*) application of diagnostic standards, and *4*) varied observation periods among study subjects. Although the effects of these factors on the outcome of long-term studies are probably self-evident, it is necessary

TABLE 1
Cumulative incidence of diabetes mellitus after gestational diabetes mellitus (GDM) by two sets of criteria

Follow-up (yr)	1st Study		2nd Study	
	n	Diabetes incidence (%)	*n*	Diabetes incidence (%)
0–1/4	308	0	229	0
1/4–1/2	301	0	150	6.6 ± 1.8
1/2–1	290	2.7 ± 0.9	147	6.6 ± 1.8
1–2	287	3.7 ± 1.1	140	8.6 ± 2.1
2–3	265	8.8 ± 1.6	92	23.7 ± 3.5
3–4	251	13.2 ± 2.0	53	38.0 ± 4.4
4–5	240	14.6 ± 2.1	31	42.3 ± 4.7
5–6	227	16.8 ± 2.2	12	52.1 ± 5.9
6–7	212	20.9 ± 2.4	2	52.1 ± 5.9

Incidence values are means ± SE. First study used ≥2 United States Public Health Service criteria cutoff points, and 2nd study used O'Sullivan and Mahan criteria for GDM (23).

to consider whether their impact is great enough to undermine any attempts at meaningful interstudy comparisons.

DIAGNOSTIC STANDARDS FOR GDM

Although many variations of diagnostic standards for GDM are used, only two have organizational backing, i.e., the World Health Organization (WHO; 3) criteria for impaired glucose tolerance (IGT) and the O'Sullivan and Mahan (1,4) criteria. The prevalence rates resulting from the application of these criteria for GDM to 752 unselected pregnant women who had 100-g oral glucose tolerance tests (OGTTs) were 7.2% by WHO criteria and 2.5% by O'Sullivan and Mahan criteria. The study group consisted of sequentially registered prenatal patients and excluded previously known diabetic patients. The O'Sullivan and Mahan criteria involve a 100-g challenge, and the WHO criteria for IGT employ a 75-g test. This prevalence exercise used a conservative adjustment of the 2-h level from 6.7 to 7.3 mM to compensate for the smaller of the two glucose challenges. The resultant prevalence rate of IGT by WHO criteria is nearly three times higher than that obtained with the O'Sullivan and Mahan criteria. It is not my purpose here to judge the relative merits of the criteria but to point out that one can logically expect that the incidence rate of subsequent diabetes will be lower for the criteria that designate the larger number of GDM patients, because a greater number of women at a lower risk will be included. To document this, two independent long-term studies of GDM utilizing criteria that give rise to different numbers of GDM patients are needed. The initial study of GDM in Boston used selection criteria based on a modification of the United States Public Health Service (USPHS) criteria for diabetes mellitus that required meeting two or more levels within the 3-h 100-g OGTT. This modification, when applied to the gestational tests of the same 752 unselected women in Boston, gave a prevalence rate of 7.25%, close to that of the aforementioned WHO criteria for IGT. Table 1 contrasts the results of this initial study with the second Boston study of GDM based on the O'Sullivan and Mahan selection criteria. It presents the actuarial projections of the incidence of diabetes mellitus subsequent to the index pregnancy for each study. The initial study based on criteria that gave the higher prevalence rate resulted in substantially fewer diabetic patients, close to one-third the number of the second study at the 4- to 5-yr follow-up.

CHOICE OF DIAGNOSTIC CRITERIA FOR DIABETES MELLITUS

The selection of a diagnostic standard obviously determines the outcome of prospective studies. The WHO criteria (3) and the National Diabetes Data Group (NDDG) (4) criteria were applied to the data from our long-term study of GDM (initial Boston study 17- to 23-yr follow-up). The WHO criteria gave an incidence rate for IGT and diabetes that was 56% higher than the rate obtained with the NDDG criteria (5).

APPLICATION OF DIAGNOSTIC STANDARDS

After choosing the diagnostic criteria, several operating decisions must be confronted. Deciding whether to require rules to exclude overt diabetes when selecting GDM patients, whether to adopt the alternative nonpregnant diagnostic standards allowed by both the NDDG and WHO criteria, and whether to embark on verification of the "known" diabetic patients encountered during follow-up are all factors that will affect the incidence rates emerging from long-term studies.

Diagnostic criteria for GDM define the lower end of the hyperglycemic range that is considered abnormal but leave the upper end undefined. The degree of gestational hyperglycemia clearly relates to subsequent incidence rates for diabetes mellitus, whether defined by levels of statistically derived criteria within a study (1) or two independent studies (Table 1) or by ranking of gestational 2-h blood glucose (6) or fasting blood glucose (FBG) (7) levels. In addition to predicting subsequent diabetes with increasing certainty, such ranking of gestational hyperglycemia predicts the proportion of women that will fail to return to a normal OGTT in the postpartum period (1,7), raising issues that complicate interstudy comparisons.

Applying the NDDG criteria, as originally described, to the long-term follow-up data from Boston gives an incidence rate ~9% lower than the same criteria described by Schuman and Spratt (8), because it does not require a second OGTT for confirmation of the diagnosis of diabetes mellitus. The modification in the WHO diabetes criteria permitting the use of a single 2-h value for epidemiological studies will certainly result in a higher prevalence rate. In general, the fewer the number of hourly intervals within a test that are required to meet individual criteria levels, the higher the prevalence of positive tests. In a random sample of OGTTs from Sudbury, MA, requiring that any three values meet the USPHS criteria cutoff points gives a prevalence of 1.2%, any two values results in a frequency of 6.6%, and any one value gives a prevalence of 13.8% (9).

Situations will also arise in which it may not be possible to apply the OGTT even though the evidence at hand does not confirm the diagnosis, e.g., diabetic patients on insulin with normal blood glucose values. Subjects stating that they already have diabetes when contacted for follow-up are often counted without critical assessment, particularly if they are on hypoglycemic treatment. Data from the prevalence study in Sudbury illustrate this potential for variation between

studies (10). The final status of the 64 subjects who came to the study stating that they were diabetic was 34 on insulin or with postprandial or postglucose hyperglycemia; 7 in remission (undisputed original diagnoses but study data all nondiagnostic); 12 with original diagnoses disputable (7) or unavailable (5) but two current abnormal values; and 11 with original diagnoses in error, disputable, or unavailable and all current study data normal. When FBG or casual blood glucose values failed to confirm the diagnosis, the original diagnostic data were traced and reviewed, and, if the diagnoses remained in dispute, one or more glucose tolerance tests were performed, if necessary, after a period without oral medications. Note that all study data were normal in 18 subjects, 7 who were considered to be in remission and were accepted, and 11 (20.8% of the stated diabetic subjects) who were excluded from the prevalence tabulation. Consequently, the uncritical acceptance of known diabetes can inflate prevalence or cumulative incidence rates of diabetes.

VARIED OBSERVATION PERIODS AMONG STUDY SUBJECTS

Investigations of chronic diseases generally cover different observation periods, often with initial enrollments occurring over years. In addition, participation at different intervals of follow-up vary, and/or permanent withdrawals almost certainly occur. As such, crude rates fail to represent the true incidence for the time span reported. Actuarial methods or denominator of person-years can be used to compensate for the resultant underreporting.

WORLDWIDE STUDIES OF DIABETES FROM GDM

Studies of the incidence of diabetes mellitus in former GDM patients are summarized in Table 2. Additional details follow, arranged in order by date of the most recent follow-up analyses and geographic location.

Sweden (1960). The definition of GDM expanded to "carbohydrate intolerance of variable severity with onset or first recognition in pregnancy" (11) qualifies for inclusion in this review the 71 cases described by Hagbard and Svanborg (12). Diagnoses were made during pregnancy in large Swedish hospitals from 1948 to 1954 when patients presented with classic diabetic symptoms (polyuria, polydipsia, weight loss, ketonuria) and fasting capillary glucose repeatedly about and >11.2 mM. Varying degrees of ketosis were present in 40% of the cases. Questionnaire investigation up to 7 yr postpartum revealed that 62% were diabetic patients on insulin. The authors segregated 37 of the 71 cases as transient, including 4 cases of coma or incipient coma, on the basis that all evidence of diabetes disappeared and glucose values returned to normal in the postpartum period. Ten (27%) of the transitory cases went on to develop insulin-requiring diabetes. The latter incidence rate is probably greatly understated based on the wide differences in individual observation periods and the reliance on questionnaire information without blood glucose testing for diagnosis. Parenthetically, the transient cases exhibited a perinatal mortality rate slightly higher than that of the permanent cases (43.2 vs. 38.2%).

Los Angeles, CA (1972). Mestman et al. (13) studied 232 women with abnormal gestational tests defined by local criteria. Observation for up to 5 yr revealed 55.6% with hyperglycemia, comprising 22.8% with two FBG values >5.6 mM and 32.8% with two of the postglucose (100 g) values meeting the levels of the Fajans and Conn (14) criteria (venous blood, glucose oxidase procedure). The incidence rate for the subset of 51 women with two FBG elevations in pregnancy was 92.2% (i.e., 58.8% with 2 FBG elevations and 33.4% with 2 postglucose elevations on follow-up).

Leningrad (1974). Although diagnostic standards are not available, a Leningrad study by Konradi and Matveeva (15) is included here because patients with normal glucose tolerance during pregnancy were also reported when followed for 0.25–6 yr after delivery. The diabetes incidence in women with "diabetic-type curves" in pregnancy was found to be over eight times higher than in those who had normal glucose tolerance (44.2 vs. 5.3%).

Belfast (1979). Hadden's (16) study of 234 women who initially met local OGTT criteria was reanalyzed. The 8 women who met WHO criteria (with 2-h blood glucose >7.2 mM) during pregnancy were retested 10 yr later, and 7 showed abnormalities in glucose tolerance. Only 1 of the 8 (12.5%) exceeded WHO standards for diabetes mellitus.

Phoenix, AZ (1980). Pettitt et al. (6) ranked third-trimester OGTTs in Pima Indians by 2-h blood glucose values and showed the levels to be increasingly predictive of 2-h blood glucose values >11.2 mM 4–8 yr later.

Aberdeen, UK (1985). The studies of Stowers et al. (17) were on 109 women who had gestational intravenous glucose tolerance tests with an increment index <2.5 and an observation period up to 22 yr (mean 12.9 yr). Approximately 35% had abnormal intravenous glucose tolerance tests, with <7% exhibiting overt diabetes.

TABLE 2
Follow-up studies of patients with gestational diabetes mellitus (GDM)

		GDM			
Ref.	Yr	*n*	Diagnostic criteria	Follow-up (yr)	DM plus IGT (%)
12	1960	71	High BG	1–7	62.0
13	1972	232	Abnormal GTT	up to 5	55.6
15	1974	43	Abnormal GTT	up to 6	44.2
		57	Normal GTT		5.3
16	1979	8	Abnormal GTT	10	87.5
6	1980	233	Abnormal GTT	4–8	4.5–45.5
17	1985	109	Abnormal IVGTT	up to 22	35.0
7	1985		Abnormal GTT:	up to 1	
		61	FBG <5.9 mM		38.0
		30	FBG 5.9–7.3 mM		67.0
		22	FBT >7.3 mM		95.0
18	1986	447	Abnormal GTT	1–12	18.8
19	1987	23	Abnormal GTT	up to 3	65.0
20	1989	261	Abnormal GTT	2–10	34.0
		40	Normal GTT		7.0
21	1989	615	Abnormal GTT	up to 28	49.9
		328	Normal GTT		7.0
22	1990	60	Abnormal GTT	3.5–6.5	78.3

Combined diabetes mellitus and impaired glucose tolerance category is not consistently defined (see text for definition and separation). BG, blood glucose; GTT, glucose tolerance test; IVGTT, intravenous glucose tolerance test; FBG, fasting blood glucose.

TABLE 3
Two studies of diabetes mellitus in former gestational diabetes mellitus (GDM) patients and control subjects by World Health Organization criteria for diabetes mellitus (WHO-DM)

Ref.	Yr	*n*	Follow-up (yr)	WHO-DM (%)
20	1989	261 GDM	2–10	18.0
		40 Control		0
21	1989	615 GDM	up to 28	36.4
		328 Control		5.5

Chicago, IL (1985). Metzger et al. (7) investigated 113 women with GDM diagnosed by the O'Sullivan and Mahan criteria. When ranked at diagnosis by three FBG levels (Table 2) and followed for up to 1 yr postpartum, by NDDG criteria, diabetes mellitus was found in 23, 43, and 86%, with 15, 23, and 9%, respectively, as the corresponding rates for IGT.

Melbourne (1986). Grant et al. (18) studied 447 pregnant women with GDM diagnosed by locally derived criteria. By WHO criteria, 1–12 yr after diagnosis, 11% were found with diabetes mellitus and 7.8% with IGT.

Stockholm (1987). A normal-weight subset of study subjects with GDM diagnosed by locally derived criteria was reported by Efendic et al. (19) and showed 65% with borderline or decreased OGTTs 6 mo to 3 yr later.

Copenhagen (1989). Damm et al. (20) reported a 2- to 10-yr (mean 5.9 yr) follow-up of 261 GDM patients and a control group of 40 nonpotential diabetic women with normal OGTTs during pregnancy. In all, 34% of women with previous GDM were found to have abnormal glucose tolerance (5% insulin-dependent diabetes mellitus, 1% NIDDM, and 12% diabetes and 16% IGT by WHO criteria). In the control group, none had diabetes, and 7% had IGT by WHO criteria.

Boston (1989). The Boston GDM study, based on two or more values of the USPHS criteria with decision rules aimed at excluding new cases of overt diabetes in pregnancy, was reported by O'Sullivan (21). The results indicated that 49.9% met the USPHS criteria for diabetes in repeated testing 22–28 yr later compared with 7% for 328 concurrent control subjects with normal OGTTs during pregnancy.

Trinidad (1990). The study by Ali and Alexis (22) was based on 157 women who met the WHO criteria for diabetes during pregnancy and had a normal OGTT postpartum. When contacted, 60 (38%) volunteered to participate in a follow-up study by interview or OGTT. A total of 61.7% had diabetes (known diabetes patients on treatment, 43.4%; diabetes by WHO criteria, 18.3%), and 16.7% had IGT by WHO criteria.

Table 3 contrasts the two studies that employed control subjects and for which follow-up data by WHO criteria were available. From all the investigations listed in Table 2, these two studies were the closest to facilitating an interstudy comparison. However, they differ by the diagnostic criteria used in the selection of GDM patients and by the observation period. Nevertheless, the progression to diabetes from GDM is impressive compared with rates from negative control subjects. The extent to which variations in the observations for individual study subjects can influence the outcome was seen when actuarial projections of the crude diabetes plus IGT rate by USPHS criteria (49.9%) resulted in an incidence rate of 73% (SE 2.8) for the GDM patients and 11.2% (SE 2.4) for the negative control subjects.

DISCUSSION

The notable fact about the worldwide studies listed in Table 2 is that only two of them used the same diagnostic criteria for GDM. All covered different time spans and presumably, at least for studies of >1 yr, had response deficiencies or varying observation periods for participants within each study. The resultant loosely categorized incidence rates exhibit a wide range of ~19–87% for diabetes plus IGT and ~6–62% for diabetes alone. When WHO criteria for diabetes are used, the two studies that employed control subjects showed incidence rates of 18–36.4% for the GDM patients and 0–5.5% for the control subjects (Table 3). Searching for geographic patterns in this wide range of differences in incidence rates becomes an exercise in futility given the potential impact of factors that were discussed at the outset and demonstrated to have quite substantial effects. However, there is broad general agreement on the predictive nature of gestational blood glucose levels. Indeed, consideration of one of the factors, the variation in individual observation periods, suggests that the rates for both GDM and control subjects could be ~50% higher than the crude incidence rates.

The second Boston study, based on the O'Sullivan and Mahan criteria, showed cumulative incidence rates for diabetes by USPHS criteria that were three times higher than those from the initial Boston study, thus indicating a primary role for the GDM selection criteria in the subsequent rate of development of diabetes (Table 1). The two studies differed primarily in the diagnostic cutoff points for the OGTT, having adopted the same exclusion rules for overt diabetes arising in pregnancy. A further emphasis of the fundamental role of the initial selection of GDM patients is seen when comparing the only two studies that used the same diagnostic criteria, i.e., the Chicago and second Boston studies. The 1-yr incidence rates for diabetes plus IGT averaged 56.6% in the Chicago study, contrasting with 6.6% in the second Boston study. The two major differences between these investigations were that *1*) only the Boston study had exclusion rules for overt diabetes and *2*) on subsequent follow-up, the two studies had different diagnostic OGTT criteria for IGT and diabetes mellitus. The NDDG diabetes and IGT standards used in Chicago are expected to give slightly lower incidence rates than the USPHS criteria used in Boston (5) and, consequently, cannot be contributing to the different rates in these studies. The Boston study excluded from the GDM category all women with classic diabetic symptoms confirmed by an abnormal OGTT or, with or without symptoms, hyperglycemia of ≥16.8 mM on two or more occasions. Presumably, the addition of this exclusion rule must account, in large measure, for the difference in 1-yr incidence rates.

A fundamental problem for incidence studies on former GDM patients is that the expanded definition of GDM accepts all degrees of hyperglycemia and ketosis as long as it has its onset or first recognition in pregnancy. Although this open-ended definition satisfies objectives related to the management of pregnancy, it also greatly complicates any

attempts at interstudy comparison of subsequent incidence rates for diabetes. In addition, the implications of this change for incidence studies can be seen when, for example, both the Hagbard and Svanborg (12) study and the Boston investigations (23) are compared with respect to the rationale for embarking on prolonged observations of GDM patients that differ so much at baseline. For patients with the severity of carbohydrate intolerance seen in the Hagbard and Svanborg study, a major research interest is to document whether any of the subjects fail to develop diabetes mellitus. On the other hand, for the Boston studies, based on asymptomatic hyperglycemia confined to pregnancy, the major research goal is to document how many develop diabetes mellitus. Both of these objectives have the possibility of clarifying our knowledge of the natural history of diabetes.

Therefore, the challenge is to achieve a consensus on standardization, not only for the selection of GDM patients but also for the reporting of results in such a way that a broad range of objectives will be fostered, including the ongoing interpretation of the effects of maternal hyperglycemia on the outcome of pregnancy and its relationship to the development of subsequent diabetes mellitus.

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