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Fasting plasma glucose to avoid a full OGTT in the diagnosis of gestational diabetes

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ABSTRACT

Aims: To evaluate the performance of fasting plasma glucose (FPG) in determining the need for a full oral glucose tolerance test (OGTT) to diagnose gestational diabetes (GDM) by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria.

Methods: A multicenter cohort study of 4926 pregnant women 20 years or older consecutively enrolled in prenatal care clinics of the Brazilian National Health Service from 1991 to 1995. All women underwent a single 2 h 75 g OGTT by weeks 24–28 of pregnancy and were followed to detect adverse pregnancy outcomes.

Results: A FPG cut-off value of 80 mg/dl indicated that only 38.7% of all women needed to undergo a complete OGTT, while detecting 96.9% of all GDM cases. When the 85 mg/dl cut-off was used, the corresponding percentages were 18.7% and 92.5%, respectively. The fraction of women labeled with GDM who had adverse pregnancy outcomes was nearly identical when using FPG strategies and universal full testing.

Conclusions: Using a FPG cut-off to diagnose GDM and to determine the need for post-load OGTT measurements is a valid strategy to diagnose GDM by IADPSG criteria. This approach may improve feasibility of applying IADPSG diagnostic criteria by reducing costs and increasing convenience.

1. Introduction

Gestational diabetes mellitus (GDM) has become an important public health problem owing to its growing prevalence and its association with adverse pregnancy outcomes and type 2 diabetes mellitus later in life. However, controversies on screening and diagnostic strategies still remain.

In 2010, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) recommended applying a diagnostic 2 h 75 g OGTT to all women reaching 24th to 28th gestational weeks and not diagnosed as having overt diabetes or GDM earlier in the pregnancy [1]. This criterion has been endorsed by the American Diabetes Association (ADA) and by the World Health Organization (WHO) for the diagnosis of gestational diabetes [2,3]. However, its poor cost-effectiveness has limited its implementation [4], so that new strategies are being considered to improve this setting.

In Brazil, a fasting plasma glucose (FPG) test has been largely used as a part of a two-step screening approach, with cut-offs between 85 mg/dl (4.7 mmol/l) and 90 mg/dl (5 mmol/l) to define a positive screening test, and thus the need for a diagnostic test (2 h 75 g OGTT) [5]. These cut-offs have been evaluated against the 1999 WHO criteria and the previous ADA

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criteria, [6,7] but to our knowledge, have been little evaluated against the IADPSG criteria [8,9]. Neither of those previous studies evaluated the ability of such a strategy to identify women who suffered adverse pregnancy outcomes during follow-up. The Brazilian Study of Gestational Diabetes (Estudo Brasileiro de Diabetes Gestacional, or EBDG) [10] an observational study which tested and followed a large number of pregnant women during a period in which diagnosis of gestational diabetes was not standardized and treatment for those with lesser than diabetes hyperglycemia was uncommon, offers a good opportunity for further evaluation.

The purpose of this study was to evaluate a strategy based on a FPG cut-off to avoid the necessity of obtaining 1 h and 2 h OGTT measurements in the diagnosis of GDM based on the IADPSG criteria.

2. Materials and methods

Analyses were based on the EBDG, a cohort of 5564 pregnant women consecutively enrolled at gestational weeks 20th–28th, and receiving prenatal care in the National Health Service in six state capitals of Brazil from May 1991 to August 1995 [10]. Ethics committees of each center approved the study protocol, and all patients gave informed consent to participate.

Eligibility criteria included having no history of diabetes outside pregnancy and being 20 years or older. At enrolment, all women answered a structured questionnaire and were scheduled for a single 2 h 75 g anhydrous glucose OGTT according to standardized WHO procedures (plasma glucose was measured in FPG, after load in 1 h and 2 h) [11]. The blood samples were collected in fluoride tubes and kept them at 4° C until centrifugation, up to 2 h later. Plasma glucose was measured by glucose oxidase method [12] in local laboratories previously certified by the Study's quality control committee. External quality controls with three different glucose concentrations were used for certification and monitoring. A coefficient of variation ≥5% at any point was a reason to suspend glucose determinations.

Body mass index (BMI) was calculated as weight (kg)/height (cm)^2 based on anthropometric measures at enrolment obtained in duplicate following a standard protocol. GDM was defined according to the IADPSG diagnostic criteria, which require only one abnormal value out of the three cut-off points: fasting ≥92 mg/dl (5.1 mmol/l); 1 h ≥180 mg/dl (10.0 mmol/l); or 2 h ≥153 mg/dl (8.5 mmol/l) [1].

Women were followed until delivery, data on outcomes being collected from chart review using a structured protocol. The composite adverse pregnancy outcome consisted of at least one of the following three outcomes: large for gestational age, preeclampsia or perinatal death. LGA was defined as a birth weight at or above the gestational age-specific (by week) 90th percentile for the study sample, as previously described [10]. Preeclampsia (or eclampsia) was defined as either chronic or incident hypertension associated with either proteinuria or convulsions after 20 weeks of gestation, in accordance with the recommendations of the National High Blood Pressure Education Program Working Group [13]. Perinatal deaths were ascertained as a fetal loss weighting more than 1 kg or with estimated gestational age >28th weeks; or an early neonatal death (up to 7 days).

Data were available for 4926 (90%) women, after excluding 566 women who did not perform the OGTT or had incomplete values for the OGTT, 21 women reaching criteria for diabetes (fasting plasma glucose level ≥126 mg/dl and/or 2 h plasma glucose level ≥200 mg/dl), 2 women who received insulin treatment, and 49 women with multiple pregnancies. Missing values for the different outcomes led to slight variation in the total sample size of specific analyses. Analyses of adverse pregnancy outcomes, due to losses during follow-up, were performed on data for 4160 women.

Data are described as absolute and relative frequencies (%) for categorical variables, and as mean and standard deviation (SD) for continuous ones. The performance of FPG in detecting GDM as diagnosed by the IADPSG criteria and in predicting the composite outcome of adverse pregnancy events was evaluated using the area under the receiver operating characteristic (ROC) curve (AUC). We calculated sensitivity, specificity, and positive and negative predictive values for FPG threshold values considered relevant as well as the percentage of women with a positive result for each threshold [14]. We employed the FPG which was part of the previously described OGTT in all analyses. The software package Statistical Analysis System (version 9.2; SAS Institute, Cary, NC) was used for all analyses.

3. Results

Main characteristics of pregnant women enrolled in the EBDG study are presented in Table 1. Means (SD) of plasma glucose for samples obtained during the OGTT were 81.5 mg/dl (4.5 mmol/l) for fasting, 121.2 mg/dl (6.7 mmol/l) for 1 h, and 103.2 mg/dl (5.7 mmol/l) for 2 h values. Prevalence of GDM was

Table 1 – Characteristics of the 4926 women participating in the Brazilian Gestational Diabetes Study.

Clinical characteristics	Mean (SD) or N (%)
Maternal age (years)	27.8 (5.4)
BMI at the enrolment (kg/m^2)	26.0 (4.0)
Gestational age at delivery (weeks)	38.4 (2.4)
Ethnicity (%)	
White	2206 (44.8)
Black	673 (13.7)
Mixed	2026 (41.1)
Other	20 (0.4)
Education (%)	
<8 years	2159 (43.9)
8–11 years	2275 (46.3)
>11 years	482 (9.8)
Parity (%)	
0	1350 (30.7)
1	1472 (33.5)
2	829 (19.0)
≥3	741 (16.8)
Family history of diabetes (%)	685 (14.8)
Cesarean delivery (%)	1624 (37.8)

Number of women for each characteristic varies slightly due to missing values.