ORIGINAL ARTICLE

Diagnostic Value of Fasting Plasma Glucose in Screening of Gestational Diabetes Mellitus

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Today, although screening tests for Gestational Diabetes Mellitus (GDM) are available, they are time-consuming and expensive; hence performing tests that are cheaper but have higher sensitivity and specificity seems necessary. The aim of this study was to determine a cut off point of fasting plasma glucose (FPG) for screening GDM.

Materials and Methods: In this clinical trial, 200 pregnant women aged ≥25 years referring to a perinatal clinic were selected. Inclusion criteria required having one of the following risk factors: History of recurrent abortion, GDM, pre-eclampsia, macrosomia, still birth, or diabetes mellitus(DM) in first degree family or pre gestational body mass index ≥25kg/m². All participants underwent a 50 g glucose challenge test (GCT) between the 24th and 28th gestational week. If 1-hour plasma glucose was over 130 mg/dL, a 3-hour 100g oral glucose tolerance test (OGTT) was recommended. The diagnosis of GDM was made based on ADA recommendations.

Results: Of 200 participants, 65 women had positive GCT, of which 58 (response rate 89%) were referred for 100g OGTT and 20 (10%) were diagnosed with GDM. The under curve area for FPG of 0.85 and the FPG level of 91.5 mg/dL, showed highest sensitivity -80%, and specificity -92%, respectively in the diagnosis of GDM. Significant difference was observed between the GDM and normal groups for mean age, gravidity, parity and BMI (P<0.05).

Conclusion: Fasting plasma glucose (FPG) ≥ 91.5 mg/dL has good sensitivity and specificity in the screening of GDM; since this is simpler and cheaper than the 50g GCT, it is recommended as a screening method for the diagnosis of GDM.

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Key Words: Fasting plasma glucose, Gestational diabetes mellitus, 50 gr glucose challenge test.

Received: 06.11.2006- **Accepted**: 06.01.2007

Introduction

Gestational diabetes mellitus (GDM), defined as glucose intolerance that begins or is first detected during pregnancy,[1-3] occurs in 1-14% of patients depending on the population described and the criteria used for diagnosis.[1,2] Early detection of this common metabolic disorder is important for prevention of maternal and prenatal complications.[1-4] The screening test consists of a one hour 50g glucose challenge test between 24-28 weeks of pregnancy and if plasma glucose level is over 130 mg/dL, it is followed by a three hour 100g glucose tolerance test.[2] Today, considering that screening tests for GDM are time-consuming and expensive, it seems necessary to perform cheaper tests with higher sensitivity and specificity. The aim of this study was determining a cut off point of fasting plasma glucose (FPG) for screening GDM in high risk Iranian women.

Materials and methods

This clinical trial was designed to evaluate 200 high risk pregnant women referring to the prenatal clinic of Imam Hospital (Sari). They had at least one of the following GDM risk factors: age ≥ 25 years old, history of recurrent abortion, GDM, preeclampsia, macrosomia, still birth, diabetes mellitus (DM) in first degree family or pregestational body mass index (BMI) ≥ 25 kg/m^2.[1,2] Pregestational overt DM was exclusion criteria. Parity and gravidity were also recorded.

All participants underwent a 50g glucose challenge test (GCT) between the 24th and 28th gestational weeks. If 1-hour plasma glucose level was over 130 mg/dL, a 3-hour 100g oral glucose tolerance test (OGTT) was recommended after at least 8 hours fasting; GDM was performed according to ADA 2006 protocol [2] (Table 1).

For diagnosis of GDM, the presence of two or more values of the glucose tolerance test is necessary; in WHO criteria the presence of one of two criteria (fasting or 2 hour glucose) is necessary for diagnosis of GDM.

According to the under curve area of receiver operating characteristics (ROC) of 77% and standard error of 0.057, the sample size considered was two hundred high risk women, approximately 20 GDM patients and 180 healthy women.

Plasma glucose concentration was assessed at the Imam hospital laboratory, using the Kubass Mira (Swiss) and Pars Azmon Kit in Imam Hospital Listratory.

Data were analyzed using SPSS 11.5 software for windows (spss Inc). ROC curves were used to construct a graphic representation of the relationship between sensitivity and specificity of a laboratory test and overall possible diagnostic cut off values. The relationship between the two groups and variables were analyzed using the student's t test and Fisher exact test; $p<0.05$ was considered significant.

Table 1. Diagnostic criteria of ADA and WHO for GDM

	ADA	ADA	WHO
Plasma glucose (mg/dL)	OGTT-100 g	OGTT-75 g	OGTT-75 g
Fasting	95	95	126
1 hour	180	180	-
2 hour	155	155	140
3 hour	140	-	-

Table 2. Basic characteristics of participants

Variable	Whole population	Healthy women	Women with GDM	p
Age (years)	27.89±5.19	27.5±5.19	31.35±3.80	0.001
Parity (number)	0.57±0.72	0.45±0.67	1±0.97	0.001
Gravidity (number)	1.68±0.91	1.62±0.67	2.25±10.7	0.003
BMI (kg/m2)	29.63±4.49	26.38±4.36	28.8±5.09	0.03

P<0.05 is significant

Results

Of the 200 participants, 65 women (32.5%) had positive GCT; 58 women (response rate 89%) had undergone the 100g OGTT; of these 20 women had GDM, according to ADA protocols, therefore the incidence rate of GDM in the cases under study was 10%. Basic characteristics of the pregnant women, are given in table 2.

Women with GDM were older (31.35±3.8 years) than women without diabetes (27.5±5.1 years, p=0.001). GDM patients had higher BMI (28.87±5.09 vs 26.38±4.36 kg/m^2, p=0.03), and were more likely to have parity (p=0.001) and gravidity (p=0.003), but there was no significant difference between the groups based on history of high risk pregnancy and a family history of diabetes.

A detailed analysis using ROC curves showed that the best cut off value for using fasting plasma glucose concentration as a screening test for gestational diabetes was 91.5 mg/dL, the under curve area was 0.85 (CI 95%: 0.73- 0.97). Using a threshold value for FPG of 91.5 mg/dL yielded a sensitivity of 80% and specificity of 92% (Fig. 1).

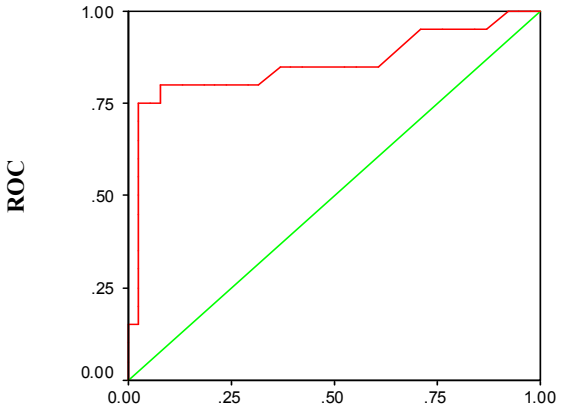

Fig.1. Area under the curve of ROC for ability of FPG in the diagnosis of GDM by OGTT 100 gr test was 0.85 with CI 0.729 to 0.976

Fasting plasma glucose (FPG) concentration at cut off value of 91.5 mg/dL had positive predictive value of 0.84 and a negative predictive value of 89%. Sensitivity was the same between FPG concentrations of 84.5 to 91.5 mg/dL (80%), while specificity increased from 69 to 92%.

The under curve areas for 1, 2 and 3 hour plasma glucose concentrations were 0.87, 0.89 and 0.68 respectively. The best threshold value for 1 hour PG with a sensitivity of 85% and a specificity of 79% was 172 mg/dL and for 2 hours PG was 146 mg/dL with sensitivity of 80% and specificity of 79%.

Discussion

The incidence rate of GDM in this study, which included pregnant women with at least one risk factor for GDM, was 10%. The incidence of GDM differs according to the population described and the race and criteria used for screening of GDM.

The under area score of ROC for fasting plasma glucoses were 0.853. Perucchini et al.[5] in their study compared the ROC of two screening tests (FPG and 50g GCT) with the golden standard of 100g OCGT; the area under the curve was 0.89 for FPG and 0.81 for GCT. The best threshold value for FPG was 86 mg/dL with specificity 76% and sensitivity of 81%. In a study by Aguiar[6] the areas under curve for FPG according to plasma glucose 1 & 2 hours and 1 & 3 hours and 2 & 3 hours were respectively 0.774, 0.749, and 0.768. FPG 93.5 mg/dL sensivity 81.3% and specificity 74.4%. Agarwal et al.[7] did a similar study in order to determine using fasting plasma glucose to diagnose gestational diabetes mellitus according to 75gr OGTT.

The population under study were all pregnant women enrolled in an international screening program of the United Arab Emirates and the area under curve in this study was 0.639; the diagnosis of diabetes was according to WHO criteria (FPG ≥ 125 mg/dL or 2 hours plasma glucose after consumption 75 gr glucose ≥ 140 mg/dL in this study more cases were diagnosed as GDM compared to 100 gr OGTT. In the Agarwal study,[7] the cut point of FPG was 84.6 mg/dL with sensitivity 78% and specificity 32.2% which is due

to the inappropriate area under curve for FPG.

In the Schrader study,[8] the relationship between pregnant outcomes and FPG, was determined and FPG of 90 mg/dL was considered an appropriate cut point.

In this study, 50 g GCT and 100 g OGCT were done for all pregnant women regardless of their risk assessment. However in our study, the cut off value for FPG was only described for 50 g GCT positive women, because it has been shown that sensitivity of 50g GCT at level of 130 mg/dL is nearly 90%,[7] thus it was not necessary to prescribe 100 g OGCT for women having less than 130 mg/dL of 1 hour plasma glucose concentrations after 50 g GCT.

The areas under the curve for 1 and 2 hour plasma glucose concentrations were appropriate. Present international (global) protocols for high risk pregnant women, it seems, need to be revised.

The area under the curve of 3 hours PG concentration clearly indicates that it lacks the appropriate sensitivity or specificity for screening GDM.

FPG $\geq$ 91.5 mg/dL has good sensitivity and specificity in screening of GDM and is simpler and cheaper than 50g GCT. Further evaluations of such screening tests with larger sample sizes are recommended.

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