

Screening for gestational diabetes mellitus in pregnant females

M. Salleh M. Ardawi, PhD, FRCPath, Hassan A. Nasrat, FRCOG, Hassan S. Jamal, MRCOG, Hussein M. Al-Sagaaf, MRCP, Bader E. Mustafa, FRCOG.

ABSTRACT

Objectives: To evaluate the applicability of the 50-g glucose challenge test as a screening test for gestational diabetes mellitus in relation to pregnancy outcomes.

Methods: A prospective study was conducted on 818 Saudi pregnant females who were randomly recruited from the Antenatal Clinics at King Abdulaziz University Hospital and New Jeddah Clinic Hospital, Jeddah. All females underwent a 50-g glucose challenge test between 24-28 weeks gestation. A result for 50-g glucose challenge test was considered positive at ≥ 7.2 mmol/L and the female was asked to undergo a 100-g oral glucose tolerance test. The diagnosis of gestational diabetes mellitus was carried out according to the National Diabetes Data Group criteria.

Results: A total of 289 females exhibited plasma glucose level ≥ 7.2 mmol/L following the 50-g glucose challenge test. Of the 289 females enrolled for the 100-g oral glucose tolerance test, 102 were diagnosed to have gestational diabetes mellitus (positive oral glucose tolerance test) and 187 were considered oral glucose tolerance test negative according to the National Diabetes Data Group diagnostic criteria. This gave a prevalence of gestational diabetes mellitus of 12.5%. Gestational diabetes mellitus females were significantly older in age, heavier in weight, with higher gravidity, greater percentage of operative deliveries and still-births, and heavier fetal birth weight as compared with the non-gestational diabetes mellitus group ($P < 0.05$ in each case). The maximum sensitivity and specificity of the 50-g

glucose challenge test were found to be at plasma glucose value of 7.8 mmol/L post the 50g glucose load. The sensitivity and specificity of this value was 88% and 84%, with a positive predictive value of 82%. To determine whether the values of plasma glucose after a 50-g glucose load were detecting abnormalities similar to those detected according to that of oral glucose tolerance test; the values obtained one-hour post the 50-g glucose challenge test were compared with zero-, one-, 2- and 3-hour values and also the area under the curve in the 100-g oral glucose tolerance test. Plasma glucose post the 50-g glucose challenge test showed marked correlation with oral glucose tolerance test results. This was mostly occurring at the one- and 2-hour oral glucose tolerance test values and was stronger in the gestational diabetes mellitus group and in both the gestational diabetes mellitus plus negative oral glucose tolerance test combined, than in the negative oral glucose tolerance test group on its own.

Conclusion: It is concluded that plasma glucose level measured one-hour post a 50-g glucose challenge test at 24-28 weeks of gestation with a cut-off value of 7.8 mmol/L is a reliable screening test for gestational diabetes mellitus in the local population studied. This test offers the best combination of ease and economy of use and reproducibility in screening for gestational diabetes mellitus.

Keywords: Gestational diabetes mellitus, screening test, 50-g glucose challenge test.

Saudi Medical Journal 2000; Vol. 21 (2): 155-160

Gestational diabetes mellitus (GDM) is a heterogeneous disorder; it is characterized by glucose intolerance with onset or first recognition

during pregnancy and if not treated is associated with adverse outcomes of pregnancy including macrosomia, higher rates of birth trauma and

From the Departments of Clinical Biochemistry (Ardawi), Obstetrics & Gynecology (Nasrat, Jamal) and Pediatrics (Al-Sagaaf), King Abdulaziz University Hospital, College of Medicine and Allied Sciences, Jeddah and the Departments of Obstetrics & Gynecology (Mustafa) and Laboratory Medicine (Ardawi), New Jeddah Clinic Hospital, Jeddah, Kingdom of Saudi Arabia.

Received 19th September 1999. Accepted for publication in final form 24th November 1999.

Address correspondence and reprint request to: Professor M.S.M. Ardawi, PO Box 9029, Jeddah 21413, Kingdom of Saudi Arabia. Tel. +00966 (2) 6932705. Fax. +00966 (2) 6952074. Mobile Tel No. 055-616-804.

metabolic complications of the newborns.¹⁻³ Hence, it is essential to use a reliable simple screening test(s) to be applied for the whole of the antenatal population (to maximize sensitivity of the test) to identify and then to diagnose GDM.⁴ There are several available screening tests for GDM including the 50-g glucose challenge test (GCT).⁵⁻⁷ This test was first described by O'Sullivan and co-workers^{6,8} as part of their screening program for GDM in which a single blood glucose estimation was made one hour after a 50-g oral glucose load. This technique enjoys a high degree of sensitivity and specificity (79% and 87%). However, whether this will apply to our local population or not is not completely known, and we believe that it is possible that an ideal screening test for a given population is not necessarily suitable for another. Other factors such as the prevalence of the disease, genetic make-up of the population, the implication of positive result and the mortality and morbidity of the disease to be screened, all are likely to affect the choice of the screening procedure.⁹ The latter is further emphasized by the recommendations of the 4th International Workshop-Conference on GDM in 1997 and indeed further work is needed in this respect in our local population.¹⁰ To further evaluate and compare the potential usefulness of the 50-g GCT as a screening test for the detection of GDM in the local population; in the present study we examined the applicability of this test in relation to pregnancy outcomes. The results are discussed in relation to the screening of GDM in the local population.

Methods. Subjects. Originally 1056 pregnant females were enrolled in the present study, however only 818 (77.5%) females completed the study. Two hundred and thirty eight (22.5%) pregnant females were excluded from the final analysis: 105 (10%) females delivered in other hospitals, 97 (9%) did not do the oral glucose tolerance test (OGTT) and 36 (3%) females had incomplete data. Therefore, a total of 818 pregnant females participated in the present study who were randomly recruited from among pregnant females attending the antenatal care clinics at King Abdulaziz University Hospital (KAUH) and New Jeddah Clinic Hospital (NJCH) between June 1996 and June 1998. Both hospitals are located in the City of Jeddah (Western part of Saudi Arabia) and serve women of diverse socioeconomic status. Age and anthropometric data together with other recorded data (maternal and fetal) of the females studied are presented in Table 1. Known risk factors for GDM were recorded: first degree family history of diabetes mellitus, previous history of GDM, 'bad' obstetric history and history of glycosuria. Females with hepatic, renal or with evident diabetes before pregnancy or who were started on dietary therapy or

who had GDM in a previous pregnancy or any other known endocrine disorders were excluded from the present study. All pregnant females studied agreed to participate in the present study and underwent a 50-g GCT between 24-28 weeks of gestation. In order to minimize the number of unnecessary OGTTs to be carried out, a threshold of plasma glucose following the 50-g GCT of ≥ 7.2 mmol/L (i.e. ≥ 130 mg/dl) was used. The latter was suggested by O'Sullivan et al⁶ by which fewer than 1% of patients would exhibit an abnormal OGTT at this threshold value. Therefore, if the results of the 50-g GCT were positive (i.e. one-hour plasma glucose ≥ 7.2 mmol/L), females were asked to undertake a 100-g OGTT. The diagnosis of GDM was carried out according to the National Diabetes Data Group (NDDG) criteria (i.e. if at least 2 values of a 100-g OGTT blood glucose $\geq 5.8, 10.6, 9.2$ and 8.1 mmol/L of fasting levels at 1, 2 and 3 hours).¹¹ Our protocol for the management of diabetes in pregnancy have been previously described.¹² The mode of delivery was recorded together with the indications for cesarian section. Newborns were examined for the following observations which were recorded for final analysis: Apgar scores, birth weight, head circumference and fetal length together with birth-weight centiles. The latter were determined using locally developed birth-weight standards. Pediatric estimation of pregnancy age and its correlation with gestational age as estimated by ultrasound or from menstrual data and any complication(s) at birth were also recorded. Moreover, other fetal outcomes were recorded as follows: fetal macrosomia (fetal weight >90 th percentile of birth weight for gestational age); low birth-weight (birth weight <2500 g); hypoglycemia (capillary glucose <1.7 mmol/L) and hyperbilirubinemia (bilirubin >180 mmol/L).

Oral glucose challenge test (50-g GCT). 50-g glucose challenge test was performed in all pregnant females who participated in the present study: pregnant females were asked to come to the Hospital not fasting and each female was administered an oral load of 50-g of glucose. One hour later, a blood sample was collected for the measurement of glucose level post the glucose load. If at one hour after a 50-g GCT, blood glucose was ≥ 7.2 mmol/L, females were asked to be scheduled for a 100-g OGTT.

100-g oral glucose tolerance test (100-g OGTT). Oral glucose tolerance test was performed in pregnant females as clinically indicated: pregnant females were asked to follow a normal diet for 3 days before the test (about 200 g/day of carbohydrate). Oral glucose tolerance test was performed after a 12-hour overnight fast. Each female to have the OGTT was administered an oral load of 100-g glucose after the collection of a blood specimen to determine fasting glucose level (i.e. zero time). Then blood samples were collected at one, 2 and 3 hours

post the glucose load. The results of the 100-g OGTT were interpreted according to the NDDG criteria.¹¹

Determination of glucose. Glucose was determined in blood samples by the glucose-oxidase method.¹³ The intra-assay coefficient of variation at 2 different glucose levels (<4.4 mmol/L and <10.0mmol/L) was 3.3% and 2.4%, and the intra-assay coefficient of variation was less than 3.9%.

Statistical analysis. Results are presented as means \pm SD and data was analyzed using SPSS-Statistical Package version 9.0 for Windows (SPSS Inc., Microsoft Corp., Chicago, IL, USA). Differences in the discrete data were assessed with Chi-squared analysis. Differences among the 3 groups were tested using the Kruska-Wallis nonparametric one-way ANOVA, pair-wise test, and differences in glucose values between the OGTT(-ve) and OGTT(+ve) groups were tested using the Whitney U-test. Comparisons between sets of data were also performed using the Student's t-test. Differences were considered statistically significant at $P < 0.05$.

Results. The mean values of the anthropometric characteristics of the various study groups are shown in Table 1. A total of 289 (35%) out of 818 females studied exhibited a plasma glucose level ≥ 7.2 mmol/L following the 50-g GCT; out of them only 102 (35%) were diagnosed to have GDM following 100-g OGTT (ie. OGTT (+ve)) and 187 (65%) were considered OGTT(-ve) according to the NDDG criteria.¹¹ This gave a prevalence of GDM of 12.5% among the females who participated in the present study. Gestational diabetes mellitus females were significantly older in age, heavier in weight, with higher gravidity, heavier fetal birth weight and greater percentage of operative deliveries and still births compared with the non-GDM group ($P < 0.05$, in each case) (Table 1). The OGTT(-ve) group was also older and slightly heavier than the non-GDM group. However, there was no difference between the 2 groups regarding the mode of delivery or the time of examination. Table 2 shows the frequency of GDM in different subsets of cut-off points of the 50-g GCT values. The maximum sensitivity and specificity of the 50-g were found at plasma glucose value of 7.8 mmol/L post the 50-g GCT load. The sensitivity and specificity of this value was 88% and 84%. The positive predictive value of this cut-off value of plasma glucose was 82%. However, the positive predictive value of plasma glucose at >10.4 mmol/L was 100%, hence making this latter value a cut-off point to ensure the diagnosis of all patients with GDM. The plasma glucose levels at all points were markedly increased in the OGTT(-ve) and GDM groups ($P < 0.05$, in each case) and were significantly different from each other ($P < 0.05$) (see Table 3). For the OGTT results, the GDM group exhibited higher

Table 1 - Maternal characteristics and fetal outcomes in Non-GDM and GDM females studied using the 50-g GCT.

Item	Groups identified using GCT and OGTT		
	Negative Screenees (N = 529)	Positive Screenees (N = 187)	GDM (n = 102)
Age (years)	29.2 \pm 4.6	30.7 \pm 4.8*	32.1 \pm 5.1*
Maternal weight (kg)	64.3 \pm 4.1	68.6 \pm 4.1	75.2 \pm 4.5*
Gravida	4.2 \pm 1.1	4.9 \pm 1.2	5.6 \pm 1.2*
Fetal birth weight (>4000g) (%)	6.3	8.1	18.9*
Fetal birth weight (<2500g) (%)	2.7	1.6	1.8
Fetal hypoglycemia (%)	0.5	1.4	8.0*
Fetal hyperbilirubinemia (%)	10.9	11.7	15.7*
Fetal birth weight (g)	3096 \pm 215	3390 \pm 201	3510 \pm 175*
Fetal length (cm)	51.2 \pm 3.9	51.1 \pm 4.8	51.3 \pm 5.1
Fetal head circumference (cm)	34.4 \pm 1.7	34.2 \pm 1.6	34.5 \pm 1.8
Cesarian delivery (%)	12.6	13.1	23.9*
Still-birth (at > 28 weeks) (%)	0.76	1.07	1.96*
Week at delivery	38.9 \pm 0.6	38.4 \pm 1.0	38.5 \pm 0.9
Week at examination	23.6 \pm 1.7	23.9 \pm 2.1	24.1 \pm 2.3
Data presented as mean \pm SD * P < 0.05 N = number			

Table 2 - The frequency of GDM in different subsets of the screening 50-g GCT.

Screening cut-off value (plasma [glucose], mmol/L)	Number	GDM	Probability of GDM (%)
≤ 7.2	529	No OGTT performed	No OGTT performed
7.2 - 7.4	35	4	11.0
7.5 - 7.7	50	18	36.0
7.8 - 8.0	36	14	39.0
8.1 - 8.3	48	20	42.0
8.4 - 8.8	74	14	19.0
8.9 - 9.4	15	4	27.0
9.5 - 9.9	4	2	50.0
10.0 - 10.4	2	1	50.0
>10.4	25	25	100.0
TOTAL	818	102	

Table 3 - The screening test examined and 100-g OGTT results in the 3 groups of pregnant females studied.

Item	Groups identified using GCT and OGTT		
	Negative Screenees (N = 529)	Positive Screenees (N = 187)	GDM (n = 102)
Screening Test:			
Glucose (mmol/L)	6.35 ± 1.26	8.4 ± 0.92*	9.65 ± 1.22*
OGTT:			
Glucose (mmol/L) at:			
Zero	-	4.82 ± 0.56	5.36 ± 0.51*
1 hour	-	8.61 ± 1.39	11.28 ± 1.25*
2 hours	-	7.35 ± 1.16	9.53 ± 1.14*
3 hours	-	5.72 ± 0.95	7.19 ± 1.39*
Results are presented as means ± SD Glucose was measured in blood samples collected one hour post 50g glucose load, or after 100g Oral glucose tolerance test as described in the Methods section. *(P<0.05)			

values than the OGTT(-ve) group. The greatest increments were observed at one (31%) and 2 (29%) hours post the 100-g glucose load (Table 3). To determine whether the 50-g GCT used as a screening test was detecting abnormalities in glucose tolerance similar to those detected according to the OGTT; the values obtained one-hour post the 50-g GCT were compared with zero-, one-, 2- and 3-hour values and also the area under the curve (AUC) in the 100-g OGTT (see Table 4). Based on the results obtained,

Table 4 - Spearman's correlation coefficients between the screening test examined and the OGTT values.

OGTT Time-interval	Group	Screening Test GCT
Zero	OGTT (-ve)	0.04
	GDM	-0.02
	Both	0.16*
1 hour	OGTT (-ve)	0.17*
	GDM	0.32*
	Both	0.27*
2 hours	OGTT (-ve)	0.18*
	GDM	0.24*
	Both	0.36*
3 hours	OGTT (-ve)	0.05
	GDM	0.06
	Both	0.10*
AUC	OGTT (-ve)	0.22*
	GDM	0.46*
	Both	0.42*
GCT - Glucose challenge test GDM - Gestational diabetes mellitus AUC - Area under the curve of OGTT OGTT - oral glucose tolerance test *(P<0.05)		

screening plasma glucose concentrations showed marked correlation with the OGTT results. This was mostly occurring at the one-, and 2-hour OGTT values, and was stronger in the GDM group ($r = 0.32$, $r = 0.24$) and in both the GDM plus OGTT(-ve) groups combined ($r = 0.27$, $r = 0.36$) than in the OGTT(-ve) group on its own (Table 4).

Discussion. Pregnancy is considered to be a state of insulin resistance and thus it may reveal subclinical defect(s) in carbohydrate metabolism that may develop into a state of carbohydrate intolerance, or GDM. If GDM is not treated, there is an increased likelihood of both maternal complications and morbidities.¹⁻³ Therefore, patients with GDM must be screened for and diagnosed early enough in the course of pregnancy to allow proper and effective therapy. Based on the results of the present study, the prevalence of GDM according to the NDDG diagnostic criteria was 12.5%. This value is much higher than that reported for Europeans,¹⁴⁻¹⁵ Americans,¹⁶⁻¹⁷ Australians,¹⁸⁻¹⁹ Indians,²⁰ Mexican Americans,²¹ Greeks²² and in Saudis living in Dammam²³ or Riyadh²⁴ areas, but lower than that reported for Zuni Indians.²⁵ The latter reflects the importance of GDM as a clinical disorder and is compatible with local epidemiological data which has shown an average prevalence rate of glucose intolerance among Saudi non-pregnant females living in the Jeddah area of 6.6-7.8%.²⁶ The purpose of a screening test in pregnancy is to subject a minimum number of females to the diagnostic test - in this case the OGTT - (high specificity) and yet to detect as many as possible cases (high sensitivity) of GDM. Also, the screening test should be well-defined, easily administered, inexpensive, and reproducible. The OGTT is considered to be the golden standard test in identifying pregnant females with GDM; however, OGTT as a screening test is impractical and considered to be cumbersome due to several factors, including length of the test, patient-unfriendly procedure, and its cost.²⁷

In the present study, a total of 285 out of 818 pregnant females exhibited plasma glucose levels ≥ 7.2 mmol/L following a 50-g GCT and only 102 females were diagnosed to have GDM according to the NDDG criteria following a 100-g OGTT (see Table 1). The maximum sensitivity and specificity of the 50-g GCT in the population studied were found to be at a plasma glucose level of 7.8 mmol/L following the 50-g glucose load. The choice of a threshold for the screening test is based on the degree of sensitivity desired and the amount of specificity to be sacrificed. In GDM, this translates into the number of OGTTs one is willing to perform to detect a given proportion of GDM cases in the population to be studied. In the classical study of O'Sullivan et al,⁶ a blood glucose

level of ≥ 7.2 mmol/L was obtained one-hour after the 50-g GCT with a 79% sensitivity and 87% specificity for GDM. Similar observations were obtained in other studies.²⁸ In the present study, when the value of plasma glucose of 7.8 mmol/L following a 50-g GCT was used as a threshold for further OGTT, the sensitivity and specificity of the screening test were 88% and 84%, with a positive predictive value at 82%. However, by lowering the threshold to 7.2 mmol/L, the sensitivity reached 93%, but the specificity decreased to 64%. Racial and geographical variations together with differences in the prevalence rates of GDM are known to influence the results of glucose screening tests in populations.^{6,29-30} This suggests that the glucose screening test threshold for exclusion of the performance of an OGTT should be determined for each population. Moreover Coustan et al³¹ proposed previously that the threshold for the 50-g GCT should be decreased to 7.2 mmol/L when the test was performed one hour post a standardized breakfast. Conversely, other reports³²⁻³³ suggested that the 50-g GCT to be performed from less than 2 hours to more than 3 hours post a non-standardized breakfast. More recently, De Los Monteros et al³⁴ showed that a threshold of 7.8 mmol/L for the 50-g GCT proposed by the NDDG was also valid when the test was performed in the fed state as it was carried out in the present study. The latter is in accordance with a better day-to-day reproducibility for this screening test.⁴

The predictive values for a screening test are usually dependent on the prevalence of the disease and also on the population under study; hence, the predictive values reported here are valid just in this specific population. The GDM group exhibited typical characteristics of the condition. Fetal birth weight was greater in GDM than in non-GDM groups. Other characteristics of the GDM group included higher: maternal age, maternal body-weight and the percentage of risk factors including family history of diabetes mellitus, operative deliveries and still-births are all consistent with the classical clinical picture of GDM patients.⁶ However, the negative glucose screen (ie OGTT(-ve)) group had neither maternal nor fetal characteristics of GDM, nor increased perinatal morbidities as described previously. When compared with negative screeners, the increases in the screening test obtained one hour post the 50-g glucose load were higher in the GDM group than in the corresponding OGTT (-ve) females: glucose, 52% vs. 32%. When the relationship between the screening test and the OGTT results were examined, the strongest correlation was obtained with the increased screening glucose levels; the latter is consistent with the original work described by O'Sullivan et al.⁶ The relationship between the post 50-g GCT screen and the OGTT values was strongest at one-, and 2-hour intervals post the 100-g OGTT and weaker with the

fasting values.

In conclusion, plasma glucose level measured one hour after a 50-g glucose load at 24-28 weeks of gestation with a cut-off value of 7.8 mmol/L is a reliable screening test for GDM in the local population examined in the present study. Moreover, the 50-g GCT offers the best combination of ease and economy of use and reproducibility in screening for and in the refining of the diagnosis of GDM.

Acknowledgments. We are grateful to King Abdulaziz University for financial support (Grant No. 104/416), to Professor M. Ardawi at the Department of Clinical Biochemistry and the Clinical Endocrine and Metabolic Research Laboratory, King Fahd Medical Research Centre, Jeddah, Kingdom of Saudi Arabia. We thank all the nursing staff at KAUH and NJCH for their help during this study and we also thank our colleagues at both hospitals for their invaluable assistance during the execution of this project. Special thanks are due to Mrs. H. Khoja for her excellent secretarial help. Special thanks are due to Dr. Hamid Mutabagani for allowing us the use of the facilities at NJCH.

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