An evaluation of the latest ADA criteria for screening and diagnosing gestational diabetes at a tertiary care hospital in the United Arab Emirates

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Abstract

The American Diabetic Association (ADA) has recently recommended lowering the cut-off values for the two-step oral glucose tolerance test (OGTT) used for screening of gestational diabetes. This study reports on the appropriateness of applying the latest ADA diagnostic criteria when screening for gestational diabetes mellitus (GDM) in a tertiary care facility in the United Arab Emirates. The study was carried out at Mafraq Hospital, Abu Dhabi, United Arab Emirates (UAE) between November 1999 and April 2001. A total of 889 pregnant women who underwent at least one test of the two-step OGTT were studied retrospectively for adverse maternal and fetal outcomes. Subjects were classified as GDM positive or negative by applying the old and the latest ADA criteria and the occurrence of adverse outcomes in the various groups was compared. Applying the latest ADA criteria with the two-step OGTT identified 11% & 17% more patients at risk for fetal and maternal adverse outcomes respectively. Advanced maternal age ($\geq$ 30 years in our population), multi-parity ($\geq$ 4) and obesity (BMI $\geq$ 30) were associated with increased risk of being diagnosed as having GDM. Application of the latest ADA criteria to the two-step OGTT was determined to be appropriate for UAE pregnant women tested for GDM in the tertiary care setting. Older (age $\geq$ 30 years), multiparous (parity $\geq$ 4), and obese women (BMI $\geq$ 30) were at greater risk of GDM diagnosis by the latest ADA criteria. (Int J Diabetes Metab 14: 55-60, 2006)

Key Words: *American Diabetic Association, gestational diabetes mellitus, glucose load test, oral glucose tolerance test.*

Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance first recognized during pregnancy.[1] The prevalence ranges from 1-14% of all pregnancies depending on the population studied and the diagnostic test employed.[2] If left untreated GDM may lead to severe neonatal and maternal complications such as still birth, fetal macrosomia, pre-eclampsia, and increased incidence of caesarean section.[3-7] Early recognition and appropriate management of GDM by dietary modifications, insulin administration, and antenatal fetal surveillance can reduce these complications.[5-8] Currently there are two strategies for screening for GDM. The first strategy - adopted by the American Diabetes Association (ADA) and the National Diabetes Data Group (NDDG) - consists of a 50g glucose load screening test (GLT) followed, among those positive in the screening test, by a 100g 3 hour oral glucose tolerance test (OGTT).[9-12] The second strategy is the WHO one step 75g 2 hour OGTT. [13,14]

Mafraq Hospital is a 500 bed tertiary referral hospital in the Emirate of Abu Dhabi, United Arab Emirates (UAE) with annual deliveries of 2500 babies. At Mafraq Hospital, the two step approach to GDM screening is offered to non-diabetic pregnant women. Recently the ADA recommended lower cutoff values for both the 50g GLT, from $\geq$ 7.8 mmol/l to $\geq$ 7.2 mmol/l, and the 100g OGTT, from 5.8 (fasting), 10.5 (1 h), 9.2 (2 h) and 8.0 (3 h) mmol/l to 5.3, 10.0, 8.6 and 7.8 mmol/l respectively [15,16] . Lowering the cut-off values has been reported to identify a greater number of pregnancies with GDM.[17,18] However, this should be weighed against the financial implications of falsely labeling a patient as GDM positive.

In the Arabian Gulf Countries diabetes mellitus is considered to be a huge public health problem. A recent national epidemiological study in Saudi Arabia revealed DM prevalence of 23.7%.[19] UAE is a multi-ethnic community with very high prevalence of GDM, obesity and multiparity.[20,21] Therefore, applying the latest ADA criteria might be justified. However, optimum cut-off values for the GLT and the OGTT to be used in this population have not been defined.

This study reports on the appropriateness of applying the latest ADA diagnostic criteria for screening of GDM using the two step approach in pregnant women seen at tertiary care facility in the UAE.

Study population and methods

The study was approved by the Research and Ethics

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Committee at Mafraq Hospital. Non-diabetic women with singleton pregnancies screened for GDM at Mafraq Hospital between November 1999 and April 2001 were the participants of this study. The 50g GLT is usually offered between 24–28 weeks of gestation, unless otherwise indicated. If the GLT is abnormal, the woman is then asked to come back for the 100g OGTT. Two or more abnormal values during the 100g OGTT are diagnostic of GDM. In the case of high risk patients, patients with poor obstetric history, positive family history for DM, or marked obesity with BMI of > 30, the 100 gm OGTT was sometimes offered without a prior 50 gm screen prior to 24 weeks gestation, and then again at 24 – 28 weeks if negative. Laboratory results for these women were collected and their hospital files were reviewed respectively for abstracting maternal and fetal demographic and anthropometric characteristics and clinical outcomes. Recorded maternal adverse outcomes included pre-eclampsia (PE) (defined as increase in systolic or diastolic blood pressure by 30 or 15 mmHg respectively with proteinuria >300 mg/day),[17] unplanned caesarean section (CS) (defined as caesarean section secondary to fetal distress or failure to progress), and induced labor. The fetal/neonatal adverse outcomes recorded were intra-uterine growth retardation (IUGR), fetal death, stillbirth, premature delivery at <36 weeks of gestation, fetal distress, fetal macrosomia (weight > 4 kg), large for gestational age (LGA), neonatal hypoglycemia (defined as capillary glucose level <1.9 mmol/l requiring glucose infusion), neonatal hyperbilirubinemia warranting phototherapy, respiratory distress syndrome (RDS) (defined as respiratory distress requiring intubation and ventilation with no evidence of sepsis), congenital anomalies, and poor Apgar score (<5 at 1 min and <7 at 5 min). Caesarean section due to previous section or twin pregnancy was considered as planned CS. The demographic, obstetric, and anthropometric characteristics of the study women are summarized in Table 1. Subjects were classified as GDM positive or not according to the old and latest ADA cut-off criteria for GLT & OGTT mentioned earlier. Maternal and fetal/neonatal adverse outcomes mentioned earlier were calculated for each group. The clinical risk factors that were evaluated in this study included nationality (UAE versus others), advanced maternal age (> 35 years), obesity (BMI > 30) & multiparity (≥ 4 deliveries).

Glucose load test

The two step screening test was performed by giving the pregnant woman a 50g glucose drink and then collecting a 2 ml blood sample in fluoride oxalate vacutainer for blood glucose analysis. Patients did not need to be fasting for this test. The 100g OGTT was done if a woman's blood glucose level in the 50g GLT was ≥ 7.8 mmol/l or if the patient had history of previous macrosomia or repeated abortion, raising the clinical suspicion of GDM following the procedure described earlier.[9] Blood was collected every hour for 3 consecutive hours after ingestion of the glucose drink using fluoride-oxalate tubes. Any woman who vomited during the test or did not complete the test was excluded from the study.

Table 1: Demographic / obstetric / anthropometric characteristics of women who took at least one of the two tests: GLT and or OGTT (n = 865)

Characteristics	Numbers	Percent %
Age group (years)		
< 25	225	26.0
25-29	193	22.3
30-34	237	27.4
≥35	204	23.6
Data missing	6	0.7
Nationality		
UAE	347	40.1
GCC Arabs	180	20.8
Non GCC Arabs	195	22.5
Others	131	15.1
Data missing	12	1.4
Parity		
0	153	17.7
1	134	15.5
2	115	13.3
3	88	10.2
≥ 4	350	40.5
Data missing	25	2.9
Pre-pregnancy Weight (kg)		
< 60	133	15.4
60-69	195	22.5
70-79	168	19.4
≥ 80	185	21.4
Data missing	184	21.3
BMI		
< 25	127	14.7
25-29	250	28.9
≥ 30	304	35.1
Data missing	184	21.3

Blood glucose estimation

Capillary blood samples were checked using the Glucotrend device (Roche Diagnostics-GmbH, Mannheim, Germany) which is calibrated to give plasma correlates. Venous blood glucose was measured with Roche Hitachi 912 & 917 clinical chemistry analyzers using the glucose oxidase method (Roche Diagnostics) after separation of the sera within 3 hours of collection.

Statistical analysis

All statistical analyses were done using the Stata software package (versions 8.0-8.2, StataCorp, College Station, Texas, USA). The statistical significance of differences between percentages was assessed using Pearson's chi-square test. Univariate odds ratios (OR) and their 95% confidence limits were calculated to examine the associations of categorical variables describing the mother, the fetus, or the neonate with dichotomized results of the women's blood glucose tests based on old and latest ADA criteria. The chi square test for trend was used to assess linear trends in ORs across levels of variables with more than two categories. Receiver Operating Characteristic (ROC) analyses were performed to identify the optimum

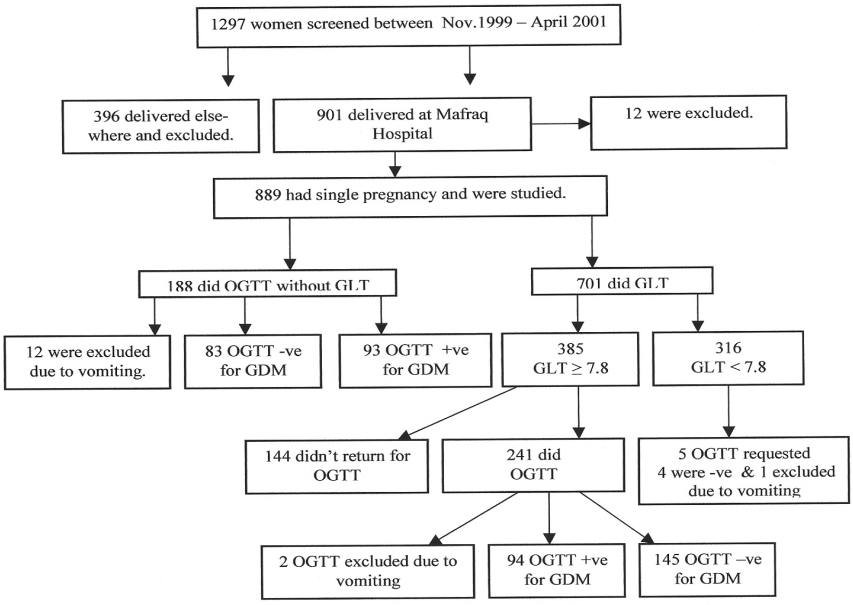


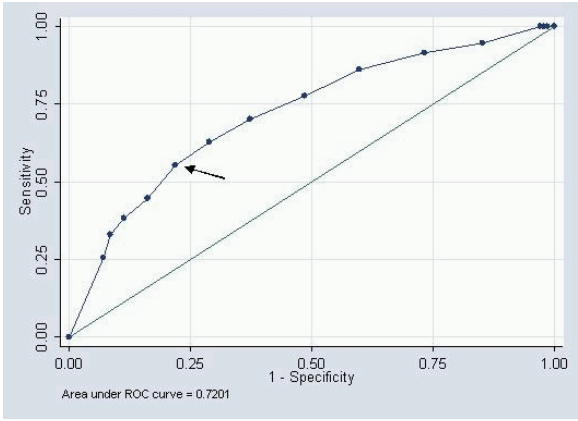
Figure 1: Study Population

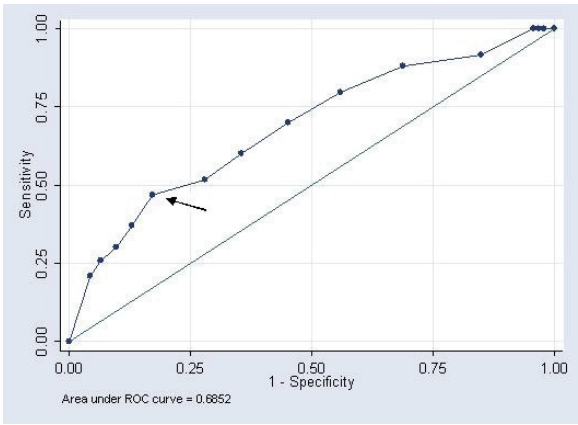
cutoff values for the GLT and the OGTT. Two-tailed P-values that were <0.05 were considered significant.

Results

A total of 1297 pregnant females were referred to Mafraq Hospital laboratory for GDM screening over the 17 months period from November 1999 to April 2001 (Figure 1). Of these women, 901 delivered at Mafraq Hospital. Of these 901 women, 12 were excluded from the study because one did not complete any of the tests and 11 had delivered twins.

Altogether, 701women underwent GLT of whom 385 were found to be positive. Of these 241 went on to have the 100g OGTT. Two patients could not complete the OGTT due to vomiting, 94 women were diagnosed as positive and 145 as negative for GDM. OGTT was performed on 188 patients without GLT screen, of whom 93 were diagnosed as positive and 83 were negative for GDM, while 12 patients could not complete the test due to vomiting and were excluded from the analysis. Five patients were screened negative by GLT but were sent back for OGTT. One of them could not complete the test and the remaining four were negative for GDM. Out of the 877 women who had at least one test done, 187 (21.3%) were diagnosed as GDM based on the old ADA criteria: 94 (10.7%) after an abnormal GLT and OGTT, and 93 (10.6%) after an abnormal OGTT (Fig. 1). By lowering the threshold value to the latest ADA criteria (≥ 7.2 mmol/l) additional 11% women were classified as having a positive GLT screen. These women experienced similar maternal and neonatal adverse outcomes as those who were tested positive for the 7.8 mmol/l threshold and the adverse outcome rates were significantly higher than those who were screened negative by the latest threshold (Table 2).





Figures 2 and 3: Receiver operator characteristic curve of GLT and OGTT

Similarly, applying the latest ADA criteria captured an additional 17% women who were positive for OGTT. These women had higher maternal and neonatal adverse outcomes, namely induction of labor, unplanned caesarean section,

Table 2: Maternal and fetal/neonatal adverse outcomes in women screened positive for GLT when applying the old and new ADA criteria

Maternal Adverse Outcomes (n = 701)	**% with adverse outcome in group positive in 50 glucose load test by threshold**			
	% positive by old ADA criteria	Additional % positive by new ADA criteria	% negative by both criteria	P Value
Pre-eclampsia (PE)	2.1	2.7	1.2	0.637
Failure to Progress	3.4	2.7	0.4	0.052
Induced Labor	10.0	6.9	1.9	0.001
Unplanned Cesarean Section	9.4	13.5	3.7	0.873
Fetal / Neonatal Adverse Outcomes				
Fetal Distress	8.1	10.8	4.6	0.108
Still Birth	0.5	0	0.4	0.821
Preterm Birth	4.9	5.4	4.6	0.949
Low Apgar 1 min	0.8	2.7	0.4	0.169
Low Apgar 5 min	0.3	0	0	0.663
IUGR	1.0	1.4	0.4	0.630
LGA	11.2	8.1	5.4	0.044
RDS	0.5	0	0.4	0.821
Neonatal hypoglycemia	10.1	1.4	1.2	0.000
Neonatal Jaundice	8.6	2.7	3.3	0.012
Congenital Anomalies	0.5	2.7	1.7	0.176

IUGR, intra-uterine growth retardation; LGA, large for gestational age; RDS, respiratory distress syndrome

Table 3: Maternal and Fetal/Neonatal adverse outcomes in women tested positive for GDM after 100g OGTT when applying the old and new ADA criteria

Maternal Adverse Outcomes (n=400)	**% with outcome in group positive in 100g oral glucose tolerance test by threshold**			
	% positive by the old ADA criteria	Additional %positive by the new ADA criteria	% negative by both criteria	Pr. Value
Pre-eclampsia (PE)	3.2	3.0	1.4	0.526
Failure to Progress	7.0	1.5	4.1	0.164
Induced Labor*	22.0	6.6	4.1	<0.0001
Unplanned Cesarean Section	15.1	4.5	8.1	0.023
Fetal / Neonatal Adverse Outcomes				
Fetal Distress	8.1	6.0	6.1	0.723
Still Birth	1.1	0	2.0	0.446
Preterm Birth	6.0	6.0	5.4	0.975
Low Apgar 1 min	1.1	1.5	2.0	0.780
Low Apgar 5 min	0.5	1.5	0.7	0.735
Intra Uterine Growth Retardation (IUGR)	0.5	0	2.0	0.266
Large for Gestational Age (LGA)	20.5	11.9	6.7	0.001
Respiratory Distress Syndrome (RDS)	0	0	2.0	0.076
Neonatal hypoglycemia	15.7	13.4	5.4	0.012
Neonatal Jaundice	16.8	9.0	6.1	0.008
Congenital Anomalies	0.5	1.5	1.4	0.690

* n =355

large for gestational age, respiratory distress syndrome, asymptomatic hypoglycaemia, and neonatal jaundice than those who were classified as negative (Table 3).

Evaluating the odds ratio across the three groups: non diabetitic, GDM by the old criteria and GDM by the latest criteria, revealed that there is a significant trend and increase in the adverse events with increasing hyperglycemia among the three groups, particularly in relation to neonatal hypoglycaemia, caesarean section delivery, large for gestational age, neonatal respiratory distress syndrome and neonatal jaundice (Table 4).

Choice of the cutoff value for GLT

Receiver Operating Characteristic (ROC) curve of the predictive ability of GLT to positive 100 gm OGTT indicated that a threshold of ≥ 9.7 mmol/l and ≥ 8.6 mmol/l is highly predictive of a positive OGTT by the old ADA and latest criteria respectively (Fig 2, 3).

Two hundred and thirty six women had 50 gm GLT followed by 100 gm OGTT. When the old ADA criteria were applied 94 women (41%) were classified as GDM. This gives a diagnostic sensitivity and specificity of 40.5% & 100% respectively for the ≥ 7.8 mmol/l threshold of the GLT with ROC area of 0.7026. When the latest ADA criteria were applied 143 women (61%) were classified as GDM with sensitivity and specificity of 61% & 100% respectively and on ROC area of 0.8069. Thus, screening test threshold at ≥ 7.2 mmol/l performs reasonably better than the old ADA criteria for GDM screening.

Table 4: Unadjusted odds ratio for maternal and fetal/neonatal adverse outcomes in women tested positive for GDM using old and latest ADA criteria

Variable	GDM Diagnosis	Unadjusted Odds Ratio	95% confidence limits of OR	Trends of Odds P-value
PIH	Non-diabetic	1.0		0.2786
	Latest ADA criteria	2.2	0.3, 16.4	
	Old ADA criteria	2.4	0.5, 12.4	
Cesarean Section	Non-diabetic	1.0		0.0327
	Latest ADA criteria	0.5	0.1, 2.0	
	Old ADA criteria	2.0	1.0, 4.1	
Fetal Distress	Non-diabetic	1.0		0.4622
	Latest ADA criteria	1.0	0.3, 3.3	
	Old ADA criteria	1.4	0.6, 3.2	
IUGR	Non-diabetic	1.0		0.1901
	Latest ADA criteria	0.0	0.0, 2.6	
	Old ADA criteria	0.3		
LGA	Non-diabetic	1.0		0.0003
	Latest ADA criteria	1.9	0.7, 5.0	
	Old ADA criteria	3.6	1.7, 7.6	
Preterm delivery	Non-diabetic	1.0		0.8366
	Latest ADA criteria	1.1	0.3, 3.8	
	Old ADA criteria	1.1	0.4, 2.8	
RDS	Non-diabetic	1.0		0.0366
	Latest ADA criteria	0.0	No data	
	Old ADA criteria	0.0		
Asymptomatic Hypoglycemia	Non-diabetic	1.0		0.0039
	Latest ADA criteria	2.7	1.0, 7.5	
	Old ADA criteria	3.3	1.4, 7.4	
Neonatal Jaundice	Non-diabetic	1.0		0.0022
	Latest ADA criteria	1.5	0.5, 4.5	
	Old ADA criteria	3.1	1.4, 6.8	

PIH: Pregnancy induced hypertension. IUGR: Intra uterine growth retardation. LGA; Large for gestational age. RDS; Respiratory distress syndrome.

Clinical risk factors as a predictor of a positive test

The odds ratio for positive GLT when applying the latest ADA criteria increased with maternal age ≥ 30 years [3.2 (2.1, 5.0)], multiparity ≥ 4 [2.9 (1.9, 4.6)] and BMI ≥ 30 [2.0 (1.3, 3.1)] respectively. For the 100 g OGTT maternal age ≥ 30 years was the only risk factor associated with increased odds ratio for a positive test 2.6(1.4, 4.9).

Discussion

The recent finding of increasing rates of maternal and fetal adverse outcomes in non-GDM pregnant women with increasing carbohydrate intolerance has led the ADA to recommend lowering the cutoff values for OGTT.[22] Our data confirm that lowering the cutoff values for GLT & OGTT in tertiary referral hospitals would have identified 11% & 17% respectively more at risk pregnancies who behave similarly to those diagnosed as GDM by the old criteria.

GDM was diagnosed in 21% of the population studied. This markedly higher rate could be explained by the fact that our hospital is a tertiary referral center. In addition not all pregnant women seen in the antenatal clinic were referred to our laboratory for screening, and not all patients screened had delivered at Mafraq Hospital. Our antenatal clinic registered 1,318 cases during the study period but we had complete records on only 877 of them (67%) assuming that all the referred cases were registered. This might imply the presence of selection bias or variation in clinical practice. Moreover, our population had a higher frequency of obese, multiparous and UAE national women - 35, 40, and 40% respectively.Maternal age ≥ 30 years appears to be an important risk factor for a positive GLT screen. This might suggest that women ≥ 30 years of age should be directed to the 100g OGTT in one step. This age is five years younger than what is reported in most of the western populations which could be due to the relatively earlier age of child bearing in the UAE and multiple pregnancies before the age of 30 years. Multiparity ≥ 4 as well as BMI ≥ 30 were also found to be of significant importance. UAE nationality did not appear to contribute to the increased risk of GDM.

We used the receiver-operator characteristic curve observation that provides quantitative measure of the truly positive and falsely negative rates for a single cutoff value. To select the optimum GLT cutoff value we looked at the value with the highest proportion of correctly classified patients with balanced maximum sensitivity and specificity. This value was found to be ≥ 8.6 mmol/l. This is different from the proposed ADA cutoff of 7.2 mmol/l. The reason for this discrepancy is due to the fact that the ROC study was performed on women who already had glucose values ≥ 7.8 mmol/l. Should the 100 gm OGTT be done on all pregnant women irrespective of the GLT value, the rates would be altered due to the increase in the proportion of subjects who do not have GDM. Therefore, we cannot recommend the use of 8.6 mmol/l cutoff value to be the threshold value. Post GLT values of > 10.8 mmol/l showed 100% specificity for GDM diagnosis by the latest ADA criteria, thus eliminating the need for the 100g OGTT on these patients. Instead these patients can return for a fasting

glucose test to confirm the diagnosis instead of subjecting them to the 100g glucose load. If those are negative or in the impaired zone, only then should the 100 g OGTT be done.

Various limitations of the study should be highlighted: Firstly, the retrospective design of the study and the fact that the outcome data were drawn mostly from medical and birth records. Secondly, the fact that not all women presenting to the antenatal clinic were offered the test, and not all those who were screened positive came back for the 100g OGTT implies some selection bias and variation in clinical practice. Thirdly, the fact that our hospital is a tertiary referral hospital suggests that the data presented cannot be generalized to the UAE population in the primary care setting without verification.

In conclusion, our findings demonstrate that applying the latest ADA criteria for screening and diagnosing GDM in the UAE will identify more patients at risk in tertiary care setting and is, therefore, justified. Studies of the primary care settings must be conducted before generalizing these criteria to that practice. Advanced maternal age, which is 30 years in our population, multiparity $\geq$ 4 and increased BMI $\geq$ 30 are associated with increased risk of the diagnosis of GDM. We recommend that patients having any of these risk factors should be referred directly the 100g OGTT in one step, or to be screened earlier than 24 weeks using the two step approach.Finally, we recommend that women with glucose values of > 10.8 mmol/l post GLT should not be subjected to the 100g OGTT. Instead these women should get a fasting blood glucose check before the 100g load is given to rule out overt diabetes.

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