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Review Article

Obstetrics and Gynaecology Section

Screening and Diagnosis of Gestational Diabetes Mellitus, Where Do We Stand

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ABSTRACT

Gestational Diabetes Mellitus (GDM) is defined as any glucose intolerance with the onset or first recognition during pregnancy. This definition helps for diagnosis of unrecognized pre-existing Diabetes also. Hyperglycemia in pregnancy is associated with adverse maternal and prenatal outcome. It is important to screen, diagnose and treat Hyperglycemia in pregnancy to prevent an adverse outcome. There is no international consensus regarding timing of screening method and the optimal cut-off points for diagnosis and intervention of GDM. DIPSI recommends non-fasting Oral Glucose Tolerance Test (OGTT) with 75g of glucose with a cut-off of ≥ 140 mg/dl after 2-hours, whereas WHO (1999) recommends a fasting OGTT after 75g glucose with a cut-off plasma glucose of ≥ 140 mg/dl after 2-hour. The recommendations by ADA/IADPSG for screening women at risk of diabetes is as follows, for first and subsequent trimester at 24-28 weeks a criteria of diagnosis of GDM is made by 75 g OGTT and fasting 5.1mmol/l, 1 hour 10.0mmol/l, 2 hour 8.5mmol/l by universal glucose tolerance testing. Critics of these criteria state that it causes over diagnosis of GDM and unnecessary interventions, the controversy however continues. The ACOG still prefer a 2 step procedure, GCT with 50g glucose non-fasting if value > 7.8mmol/l followed by 3-hour OGTT for confirmation of diagnosis. In conclusion based on Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study as mild degree of dysglycemia are associated with adverse outcome and high prevalence of Type II DM to have international consensus It recommends IADPSG criteria, though controversy exists. The IADPSG criteria is the only outcome based criteria, it has the ability to diagnose and treat GDM earlier, thereby reducing the fetal and maternal complications associated with GDM. This one step method has an advantage of simplicity in execution, more patient friendly, accurate in diagnosis and close to international consensus. Keeping in the mind the diversity and variability of Indian population, judging international criteria may not be conclusive, thus further comparative studies are required on different diagnostic criteria in relation to adverse pregnancy outcomes.

Keywords: Criteria, DIPSI, IADPSG, Outcome, WHO

INTRODUCTION

Any degree of glucose intolerance with the onset or first recognition during pregnancy is defined as Gestational Diabetes Mellitus (GDM) [1]. Women with history of GDM are at an increased risk of adverse maternal and perinatal outcome and also at increased risk of future diabetes predominantly Type II including their children and therefore there are two generations at risk [2]. Any degree of glucose intolerance during pregnancy is associated with adverse maternal and fetal outcome. The adverse maternal complications include hypertension, preeclampsia, urinary tract infection, hydramnios, increased operative intervention and future DM. In the fetus and neonates it is associated with macrosomia, congenital anomalies, metabolic abnormalities, RDS, etc. and subsequent childhood and adolescent obesity [3]. Therefore, it is important to diagnose early and treat promptly to prevent complications. GDM is a topic of considerable controversy when it comes to its screening, diagnosis and its cost-effectiveness. Precise level of glucose intolerance characterizing GDM has been controversial over three decades.

High prevalence of DM and genetic predisposition to metabolic syndrome among Asians, particularly in Indian women, predisposes women to develop GDM and its complications. So, there is a need for cost-effective universal screening and diagnostic method. Unfortunately there is no international consensus on the screening and diagnostic criteria for GDM. The rationale of this review is to provide recent updates and to discuss the controversies of screening and diagnosis of GDM. It affects 7% of all pregnancies worldwide and in India it ranges from 6 to 9% in rural and 12 to 21% in urban area [4]. The high rate implies that Indian population has a higher incidence of DM and impaired glucose tolerance and is at a greater risk of developing GDM. It is diagnosed at 16.3% in ≤ 16 weeks of gestation, 22.4% between 17-23 weeks and 61.3% after 23 weeks of gestation [5]. The HAPO study demonstrate that maternal hyperglycemia even at a level below that diagnostic of DM is associated with increased birth weight and macrosomia. An increase in morbidity during pregnancy with a likelihood of developing diabetes in future is associated with maternal hyperglycemia. This also has a direct impact on the developing fetal pancreas and remains a risk factor for developing DM in future [6].

Who should be screened for GDM: Previous reviews were not definite whether to do universal screening or risk based screening. American Diabetes Association (ADA) states that low risk women, those with age less than 25 years, not a member of ethnic group, BMI 25kg/m^2 or less, no previous history of abnormal glucose tolerance or adverse obstetrics outcomes and no known history of diabetes in first degree relatives, in these women there is no need to screen and less likely to benefit from any screening [7]. In risk based screening GDM was found in 1.45% of women as against universal screening which showed 2.7% in the same population showing that risk based screening has missed half of the GDM [8]. Based on these facts there is a need for universal screening especially in South east Asians countries more so in Indian women as they have high prevalence of Type II DM and genetic predisposition.

When to screen: Screening for GDM is usually done at 24-28 weeks of gestation because insulin resistance increases during the second trimester and glucose levels rise in women who do not have the ability to produce enough insulin to adopt this resistance.

Placental hormones mediate insulin resistance which increases GDM as the pregnancy advances so testing too early may not be helpful in some patients. Similarly, performing tests too late in third trimester limits the time in which metabolic interventions can

take place. Because of these reasons, it is advised to perform the tests at 24-28 weeks of gestation. The recommendations given by International Association of Diabetes and Pregnancy Study Group (IADPSG) which was endorsed by ADA based on Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study is to do on the first prenatal visit, fasting plasma glucose, HbA1C or random plasma glucose in all women. If results are not diagnostic of overt DM and fasting plasma glucose ≥ 92 mg/dl diagnosis of GDM is made. If fasting glucose is < 92mg/dl at the first antenatal visit a 2-hour 75g OGTT should be repeated at 24-28 weeks [9].

Screening and Diagnostic Criteria: In 1960, O' Sullivan et al., proposed that screening, diagnosis and treatment of Hyperglycemia in women who are not a known DM improve outcomes. They proposed diagnostic criteria for GDM based on 3-hour 100g glucose OGTT and then they validated these criteria for the development of future DM in the mother [10]. There is no consensus regarding screening and diagnostic methods for GDM. Screening and diagnostic methods can be universal or risk based one step or two step procedure. Risk factors for GDM include obese women, BMI above 30 kg/m^2, previous macrosomic baby weighting 4.5 kg or above, previous GDM, family history of DM (first degree relative with DM), ethnic family origin with a high prevalence of DM, clinical conditions associated with insulin resistance like PCOD, acanthosis nigricans, history of hypertension or hypercholesterolaemia.

World Health Organization (WHO) [11]. In 1999 defined and classified criteria for the diagnosis of GDM. These include:

1. GDM is a carbohydrate intolerance resulting in Hyperglycemia of variable severity with the onset or first recognition during pregnancy.
2. In first and early second trimester fasting and postprandial glucose concentrations are normally lower than in normal non-pregnant women. Elevated fasting or postprandial plasma glucose levels at this time in pregnancy may well reflect the presence of DM which has antedated the pregnancy.
3. Testing for GDM usually done between 24-28 weeks of gestation.
4. To determine if GDM, is present a standard OGTT should be performed with 75g anhydrous glucose in 250-300ml of water after overnight fasting of 8-14 hours. Plasma glucose is measured, fasting and after two hours, pregnant women who meet the criteria for DM or Impaired Glucose Tolerance (IGT) are classified as having GDM. These women should have 75g OGTT at 6 weeks or more after delivery. A venous plasma glucose cut off of ≥140 mg/dl (7.8mmol/l) at 2-hour are classified as having GDM. It became popular particularly in developing countries as it is simpler than two step procedure [11].

DIPSI (Diabetes in Pregnancy Study Group India)

A universal screening which is simple, feasible, acceptable and a single step procedure is applicable in Indian scenario as Indian women have an eleven fold increased risk of developing glucose intolerance during pregnancy. When compared to Caucasian women and also among ethnic group in south Asian countries, Indian women have the high frequency of GDM [12].

Seshiah et al., recommended DIPSI as a single step procedure irrespective of the last meal. Pregnant women attending the antenatal OPD were given 75g anhydrous glucose in 250-300ml of water and plasma glucose was estimated after 2 hour. A 2-hours plasma glucose ≥ 140 mg/dl is taken as GDM. [13] However, the cut off has not been put to test to find the correlation with adverse perinatal outcome. A value of ≥ 200 mg/dl as DM and ≥ 120 mg/dl as decreased gestational glucose tolerance (DGGT) has been suggested [Table/Fig-1].

Rationale for Non-fasting status OGTT: Adequate and brisk insulin response in normal women maintains euglycaemic state despite glucose challenge where as women with GDM have an increase in glycaemic levels with glucose challenge due to impaired insulin secretion [14].

Criteria	In Pregnancy	Outside Pregnancy
2hours ≥ 200 mg/dl	Diabetes Mellitus	Diabetes Mellitus
2hours ≥ 140 mg/dl	GDM	IGT
2hours ≥ 120 mg/dl	DGGT	

[Table/Fig-1]: DIPSI Criteria for diagnosis of GDM (75 gm OGTT).
DGGT–Decreased gestational glucose tolerance, IGT – Impaired glucose tolerance

Advantages Claimed are single step for screening and diagnosis of GDM, second visit not necessary for diagnosis, least disturbances to routine activity and economical.

Studies Against Doing DIPSI Non-fasting

1. Low sensitivity, study by Mohan et al., on 1,031 pregnant women attending antenatal OPD compared DIPSI, WHO (1990) and IADPSG criteria found that 83 women were identified to have GDM by WHO (1990), 23 by DIPSI and 106 by IADPSG. They concluded that the DIPSI non- fasting OGTT criteria cannot be recommended for the diagnosis of GDM due to low sensitivity. Single step fasting OGTT should be done and when this is not possible the well established two step procedure using 50 g GCT followed by 100 g OGTT can also bee done [15]. Vijayalakshmi et al., in their study of 200 pregnant women to find the effectiveness of DIPSI diagnostic criteria for GDM found 22 women had GDM based on DIPSI criteria. Out of these only 5 women had abnormal ADA recommended OGTT criteria showing that 17 women were wrongly categorized as GDM based on DIPSI criteria [16].
2. Venous plasma glucose values also depend on the timing of the day when it was done. Lee et al., in their study observed that glucose tolerance decreases in the afternoon and evening as detected by glucose tolerance tests. Reduced insulin sensitivity and beta cell response to glucose both account for this deterioration of glucose tolerance later on the day giving rise to false positives [17]. Goldberg et al., in their study found that women with positive glucose challenge test which was done in the afternoon were likely to have GDM than those with a positive test done in the morning suggesting that time of performance of OGCT will influence the results and give rise to false positive results which will lead to unnecessary diet control, insulin therapy, regular follow-up and anxiety [18].
3. Pulkit et al., in their retrospective study of comparison of DIPSI and IADPSG criteria for diagnosis of GDM in 152 pregnant women observed that 113 (74.34%) were diagnosed as GDM with DIPSI and only 34(22.36%) were diagnosed as GDM with fasting glucose alone. Including 2 hours plasma glucose as ≥ 153mg/dl, 69 (45.39%) were detected as GDM. Diagnosis of GDM by DIPSI leave 22.36% undiagnosed cases which can easily be detected using IADPSG criteria and concluded that IADPSG criteria is better for screening GDM than DIPSI as it missed substantial number of patients [19]. Studies by Seshiah et al., who are in favour of DIPSI suggest it is a better single step screening and diagnostic procedure, economical and easy to perform. Glucose challenge test with 50 gm glucose lacks specificity and leaves 21.5% cases as undiagnosed. The two step procedure requires at least two visits and 3-5 blood samples to be drawn [13].

International Association of Diabetes and Pregnancy Study Group (IADPSG) Criteria [20]

In the year 2008 an international multicentre cohort study was done, comprising of 25,505 pregnant women, who were tested with a 2-hour 75g OGTT and were followed throughout

pregnancy to detect primary and secondary outcomes (HAPO study). The study demonstrated an association between plasma glucose levels and adverse pregnancy outcomes. The analysis was done after adjusting multiple potential confounders and these associations were independent of other known risk factors for these outcomes [20].

IADPSG consensus panel after reviewing the results of HAPO and other studies which were associated with maternal glycaemia and perinatal and long term outcomes in offspring recommended the most commonly used guidelines for the diagnosis of GDM.

These cut off represent the average glucose values at which the odds for birth weight is >90th percentiles, cord C-peptide >90th percentile and neonatal percent body fat >90th percentile reached 1.75 times the odds of these outcomes at the mean glucose values based fully adjusted logistic regression models [9].

Guidelines	Fasting PG Mg/dl (mmol/l)	Glucose Challenge	1-hour PG Mg/dl (mmol/l)	2-hour PG Mg/dl (mmol/l)	3-hour PG Mg/dl (mmol/l)
WHO 1999#[11]	≥ 126 (7.0)	75 g OGTT	Not required	≥ 140 (7.8)	Not required
ACOG ##[21]	≥95(5.3)	100gOGTT	≥180(10.0)	≥155 (8.6)	≥ 140(7.8)
Canadian Diabetes Association###[22]	≥95 (5.3)	75 g OGTT	≥191(10.6)	≥ 160(8.9)	Not required
IADPSG####[9]	≥ 92 (5.1)	75g OGTT	≥180(10.0)	≥ 153 (8.5)	Not required
DIPSI#[13]	Not required	75g OGTT	Not required	≥140 (7.8)	Not required

[Table/Fig-2]: Diagnostic Criteria for GDM with their respective glucose values.
#One value sufficient for diagnosis, ##Two or more values required for diagnosis
###Two or more values required for diagnosis, ####One value is sufficient for diagnosis

For IADPSG criteria an OGTT is done in the fasting state using 75 g of glucose at 24-28 weeks and GDM diagnosed if any one of the following cut-off is met i.e. ≥ 92 mg/dl (≥ 5.2 mmol/l) or 1-hour ≥ 180 mg/dl (≥ 10 mmol/l) or 2-hour ≥ 153mg/dl (≥ 8.5 mmol/l) [9]. The criteria for diagnosis of GDM are summarized in [Table/Fig-2].

These criteria were endorsed by WHO (2013) and American Diabetes Association (ADA) except National Institute of Health (NIH) stating it needed more evidence for adoption. Following NIH report in 2014, the ADA has offered two options either one step IADPSG or the two step procedure.

American Diabetes Association (ADA), 2015 Criteria [23]

Two methods proposed by ADA for the diagnoses of GDM in women without pre-existing Diabetes,

"One Step" Procedure": Performing OGTT in the morning after overnight fast of ≥ 8 hours, 75g OGTT with plasma glucose (PG) measurement fasting, 1-hour and 2-hour at 24-28 weeks in women not having preexisting diabetes, GDM is diagnosed if PG values equals or exceed:

Fasting serum glucose of 92mg/dl (5.1mmol/l)
1-hour serum glucose of 180mg/dl (10.0mmol/l)
2-hour serum glucose of 153mg/dl (8.5mmol/l)

"Two Step" Procedure": Step one performing 50 gram glucose challenge test irrespective of last meal at 24-28 weeks in women not having preexisting diabetes, if PG at 1-hour after load is ≥ 140mg/dl (7.8mmol/l) proceeded to 100g glucose OGTT. Step two performed while patient is fasting GDM diagnosis is made when two or more PG levels equals or exceeds:

Fasting serum glucose of 95 mg/dl or 105 mg/dl (5.5/5.8 mmol/l)
1-hour serum glucose of 180 mg/dl or 190 mg/dl (10.0 / 10.6 mmol/l)
2-hour serum glucose of 155 mg/dl or 165mg/dl (8.6 / 9.2 mmol/l)
3-hour serum glucose of 140 mg/dl or 145 mg/dl (7.8 /8.0 mmol/l)

Current ADA guidelines recommended selective screening of high risk women for GDM, where as ACOG guidelines advice universal screening and NICE guidelines recommended screening all women of south Asians ethnicity.

The use of IADPSG resulted in increased prevalence of GDM rate 35.5% versus 10.6% with "two step" procedure, significant improvement in pregnancy outcome and also cost-effectiveness [24]. The drawbacks of IADPSG criteria for diagnosis of GDM is based on single value of glucose above the cut off which may cause more number of false positive GDM cases compared with Carpenter and Coustan criteria which requires 2 or more glucose values more than the cut off for diagnosis.

Based on the IADPSG cut off, only 9.3% were diagnosed as GDM if any two values of glucose above the cut off were taken as positive. This has led to four times decrease in the number of women being diagnosed as GDM as compared with 42% using a single value [25]. One of the biggest criticism about the IADPSG criteria has been that it increases the number of women diagnosed as GDM as it uses a rather low fasting plasma glucose cut off.

In the WHO 1999 criteria a fasting plasma glucose (FPG) level of ≥ 7.0 mmol/l is universally considered to be too high which has led to some groups use only 2 hours plasma glucose measurement without FPG while other used both measurement. There was need to update WHO criteria [11]. In the WHO 2013 diagnostic criteria, GDM should be diagnosed at any time in pregnancy if one or more of the following abnormality are met, fasting plasma glucose 5.1 – 6.9 mmol/l (92 – 125 mg/dl), one hour plasma glucose ≥ 10.0mmol/l (180mg/dl), 2-hour glucose 8.5 -11 mmol/l (153-199 mg/dl) after overnight fasting with 75g glucose load [26].

NICE Guidelines 2015 for Screening and Diagnosis of GDM [27]

1. Assess risk of GDM using risk factors in a healthy population. If women had GDM in previous pregnancy do 75g OGTT as soon as possible, if negative repeat again at 24-28 weeks. Other women with any other risk factors screen at 24-28 weeks by 2-hour OGTT with 75 g glucose load.
2. Do not use fasting plasma glucose, random blood glucose, HbA_1C, glucose challenge test or urine analysis for glucose to assess risk of developing GDM.
3. Glycosuria of 2+ or more on one occasion or of 1+ or above on 2 or more occasions by regent strip on ANC needs further testing to exclude GDM.
4. Diagnosis of GDM made if the women has either fasting plasma glucose level of 5.6mmol/l or above or a 2-hour plasma glucose level of 7.8mmol/l or above.

By seeing all these criteria and guidelines where do we stand? What would be ideal in developing and developed countries is still a question. What is needed is a correct diagnosis, prompt treatment to prevent adverse maternal and perinatal outcome and development of future diabetes both in mother and child. Will a single glucose value be diagnostic to serve as a standard of care? If a single glucose determination such as fasting plasma glucose or any other value would have been sufficient for the diagnosis a full OGTT can be avoided. The relative independent contribution of the fasting, 1-hour and 2-hour glucose values were considered by IADPSG in concordance with HAPO trial. Each of these values contributed at least partially as an independent predictor of adverse outcome and therefore IADPSG, recommended the full 2-hour 75g OGTT.

Among HAPO cohort, 11.1% had only one elevated result, 3.9% had 2 elevated results and 1.1% had elevation of all these results. Diagnosis of GDM by a single glucose value may be acceptable in low resource community with a cost of decreased sensitivity which will exclude many women with GDM from being diagnosed and deny them the benefit of treatment [28].

In 2012 Wings (Women in India with GDM Strategy) started by International Diabetes Federation (IDF) to develop a model care

for GDM and to find a cost-effective way of screening for GDM. The outcome of the study was that DIPSI non-fasting OGTT criteria, even though high in specificity, had a very low sensitivity (27.7%) when compared to WHO (1999) criteria and even lower in comparison with the IADPSG criteria (2.6%). The low sensitivity of the non-fasting DIPSI OGTT is not suitable for diagnostic test and makes fasting 75g OGTT new WHO guidelines to be ideal, which recommended the IADPSG criteria. Fasting plasma glucose estimation can be done in the pregnant women at early gestation, if it is normal i.e. 92mg/dl repeat single step OGTT at 24-28weeks with 75 g glucose in fasting state and apply IADPSG criteria to diagnose GDM. If fasting is 92-125mg/dl it is diagnosed as GDM and if it is ≥ 126mg/dl it is designated as overt Diabetes. To obtain International standardization it is recommended to do a one step fasting OGTT using 75g glucose and apply IADPSG criteria and keeping in mind the 2 step as an alternative procedure [15].

Considering Indians, who belongs to high risk ethnic group with high prevalence of diabetes, the worldwide recommendations go in favour of universal screening at first registration. The IADPSG criteria is the only outcome based criteria, it has the ability to diagnose and treat GDM earlier, thereby reducing the fetal and maternal complications associated with GDM.

This one step method has advantage of simplicity in execution, more patient friendly, accurate in diagnosis and close to international consensus. However, in low resources set up and in rural areas where it is not feasible to carry out the above mentioned screening program then DIPSI is recommended as a one step glucose value testing with least disturbance to patient's routine activities and may still be valuable keeping in mind the low sensitivity and diurnal variation.

CONCLUSION

Screening and diagnosis of GDM and treating it effectively not only prevent adverse maternal and perinatal outcome but also future diabetes in both mother and child. Whatever method used it is important to do universal screening in Southeast Asians countries. More effective and simpler strategies should be developed in future clinical practice by which the need for performing an OGTT can be avoided In HAPO study risk of adverse outcomes were very low when fasting plasma glucose was ≤ 4.4mmol/l (80mg/dl). Further evaluation is required before recommending FPG as a screening method which may potentially identify pregnancies with very low risk of GDM. After reviewing all the related articles on GDM, one important aspect which comes to mind is that the Indian population is diverse and variable, hence judging international criteria on Indian population may not be conclusive. So we need further comparative study on different diagnostic criteria in relation to pregnancy outcomes.

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