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UPDATE ARTICLE

National Guidelines to Diagnose GDM

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Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (1). Women with a history of GDM are at increased risk of future diabetes, predominantly type 2 diabetes, as are their children (2). GDM may play a crucial role in the increasing prevalence of diabetes and obesity (3). The highest prevalence was found in the South-East Asia Region at 25.0%. More than 90% of cases of hyperglycaemia in pregnancy are estimated to occur in low- and middle-income countries (4). Therefore all pregnant women should be screened for GDM, even if they have no symptoms, according to new recommendations (5). For this the diagnostic procedure has to be simple to perform, economical and evidence based.

Screening and Diagnosis

Compared to selective screening, universal screening for GDM detects more cases and improves maternal and neonatal prognosis(6). Hence, universal screening for GDM is essential, as it is generally accepted that women of Asian origin and especially ethnic Indians are at a higher risk of developing GDM and subsequent type 2 diabetes(7).

Diagnostic Procedures

[A] World Health Organization Procedure (Old)

To standardize the diagnosis of GDM, the World Health Organization (WHO) recommends using a 2-hour 75 g oral glucose tolerance test (OGTT) with a threshold plasma glucose concentration of greater than 140 mg/dL at 2 hours, similar to that of IGT (> 140 mg/dL and < 199 mg/dL), outside pregnancy(8).

[B] The International Association of the Diabetes and Pregnancy Study Groups (9)

Based on the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, International Association of the Diabetes and Pregnancy Study Groups (IADPSG) suggested the guidelines. In this HAPO study, population from India, China, South Asian countries (except city of Bangkok, Hong Kong), Middle East and Sub Saharan countries were not included. Thus, essentially HAPO study was performed in Caucasian population.

- The IADPSG recommends that diagnosis of GDM is made when any of the following plasma glucose values meet or exceed: Fasting: ≥ 5.1 mmol/L (92 mg/dL), 1-hour: ≥ 10.0 mmol/L (180 mg/dL), 2-hour: ≥ 8.5 mmol/L (153 mg/dL)7 with 75 g OGTT. Though one value is recommended to diagnose GDM the procedure requires 2hr OGTT, thus not cost effective(9).
- The IADPSG also suggests: Fasting plasma glucose (FPG) > 7.0 mmol/L (126 mg/dL)/A1C > 6.5% in the early weeks of pregnancy is diagnostic of overt diabetes. Fasting > 5.1 mmol/L and < 7.0 mmol/L is diagnosed as

GDM(10).

Disadvantages of the IADPSG suggestions are:

[1] Most of the time pregnant women do not come in the fasting state because of commutation and the belief,'not tofast for long hours'.

[2] The dropout rate is very high when a pregnant woman is asked to come again for the glucose tolerance test(11).

[3] Attending the first prenatal visit in the fasting state is impractical in many settings(10).

[4] In all GDM, FPG values do not reflect the 2-hour post glucose with 75 g oral glucose [2-hour plasma glucose (PG)], which is the hallmark of GDM(12).

[5] There is no high quality evidence that women and their fetuses benefit from treatment if only the fasting value is abnormal.RCT shows benefit of treating GDM women identified primarily by post load values (13).

[5] Ethnically Asian Indians have high insulin resistance and as a consequence, their 2-hour PG is higher compared to Caucasians(14).

[6] The insulin resistance during pregnancy escalates further(15) and hence FPG is not an appropriate option to diagnose GDM in Asian Indian women.

[7] In this population by following FPG > 5.1 mmol/L as cut-off value, 76% of pregnant women would have missed the diagnosis of GDM made by WHO criterion(16).

[8]Asian and South Asian ethnicity are both independently associated with increased insulin resistance in late pregnancy. A diagnostic FPG was present in only 24% of those with GDM in Bangkok and 26% in Hong Kong(17).

[9] Center to center differences occur in GDM frequency and relative diagnostic importance of fasting, 1-hour and 2-hour glucose levels. This may impact strategies used for the diagnosis of GDM(17).

[10] With IADPSG criteria the frequencies of GDM show substantial variability between and within regions of the world. The variations may influence the future development of optimal, cost-effective strategies for detection and treatment of GDM(18).

[C] A Single Test Procedure to Diagnose GDM in the Community (Diabetes in Pregnancy Study Group India)(19)

Note: Diabetes in Pregnancy Study Group India (DIPSI diagnostic criteria 2-hour PG ≥ 140 mg/dL is similar to WHO criteria 2-hour PG ≥ 140 mg/dL to diagnose (8).

"A Single-step procedure" was developed due to the practical difficulty in performing glucose tolerance test in the fasting state, as seldom pregnant women visiting the antenatal clinic for the first time come in the fasting state. If they are asked to come on another day in the fasting state, many of them do not return(20). Hence, it is important to have a test that detects the glucose intolerance without the woman necessarily undergoing a test in the fasting state, and it is preferable to perform the diagnostic test at the first visit itself.

Procedure

In the antenatal clinic, a pregnant woman after undergoing preliminary clinical examination, has to be given a 75 g oral glucose load*, irrespective of whether she is in the fasting or nonfasting state and without regard to the time of the last meal. A venous blood sample is collected at 2 hours for estimating plasma glucose by the GOD-POD method. GDM is diagnosed if 2-hour PG is ≥ 140 mg/dL (7.8 mmol/L).

If 75 g glucose packet is not available, remove and discard 5 level teaspoons (not heaped) of glucose from a 100 g packet which is freely available. In hospitals where glucose is supplied in bulk, a cup or container of 75 g may be used. The glucose marketed is in anhydrous form.

Performing this test procedure in the nonfasting state is rational, as glucose concentrations are affected little by the time since the last meal in a normal glucose tolerant woman, whereas it will, in a woman with gestational diabetes(21). After a meal, a normal glucose tolerant woman would be able to maintain euglycemia despite glucose challenge due to brisk and adequate insulin response, whereas, a woman with GDM who has impaired insulin secretion(22), her glycemic level increases with a meal and with glucose challenge, the glycemic excursion exaggerates further(23). This cascading effect is advantageous as this would not result in false-positive diagnosis of GDM.

Advantages of the DIPSI procedure are:

• Pregnant women need not be fasting(24).
• Causes least disturbance in a pregnant woman's routine activities
• Serves as both screening and diagnostic procedure.

This single-step procedure has been approved by Ministry of Health, Government of India(25) and also recommended by WHO.

While WHO is endorsing IADPSG criteria as new WHO criteria 2013, it also recommends "A Single Step Procedure" to diagnose GDM.

WHO also has made a few important and pertinent observations:

A] OGTT is resource intensive and many health services, especially in low resource settings, are not able to routinely perform an OGTT in pregnant women. In these circumstances, many health services do not test for hyperglycemia in pregnancy.

B] For a pregnant woman, the request to attend fasting for a blood test may not be realistic because of the long travel distance to the clinic in many parts of the world, and increased tendency to nausea in the fasting state. Consequently nonfasting testing may be the only practical option (26).

C] A 2-step procedure requiring attendance on 2 separate occasions is often not feasible in many low and middle income countries.

D] Laboratory glucose measurement is often not available and testing with a portable blood glucose meter is the only option. (DIPSI also recommends plasma glucose calibrated glucometers).

E] The A1C is not possible to perform in the less resource countries, not only because it is expensive but also due to lack of technically qualified staff. The cost and standardization of A1C testing are issues for consideration(10).

[D] National guidelines 2014 - Protocol

- Testing for GDM is recommended twice during ANC. The first testing should be done during first antenatal contact as early as possible in pregnancy.
- The second testing should be done during 24-28 weeks of pregnancy if the first test is negative. There should be at least 4 weeks gap between the two tests.
- The test is to be conducted for all PW even if she comes late in pregnancy for ANC at the time of first contact.
- If she presents beyond 28 weeks of pregnancy, only one test is to be done at the first point of contact.
- If the test is positive at any point, protocol of management should be followed as given in this guideline. At MC/DH/other CEmOCCentres, availability of glucometer must be ensured at all ANC clinics with facility for collection of sample and interpretation of result there itself (by training of personnel).
- At all other facilities upto PHC level, there should be an in-house arrangement for conducting the test & giving report immediately so that necessary advice can be given on the same day by the treating doctor.

[i] Methodology: Test for diagnosis

Single step testing using 75 g oral glucose & measuring plasma glucose 2 hour after ingestion. 75g glucose is to be given orally after dissolving in approximately 300ml water whether the PW comes in fasting or non-fasting state, irrespective of the last meal. The intake of the solution has to be completed within 5 min.A plasma standardized glucometer should be used to evaluate blood glucose 2 hours after the oral glucose load. If vomiting occurs within 30 min of oral glucose intake, the test has to be repeated the next day, if vomiting occurs after 30 minutes, the test continues. The threshold plasma glucose level of ≥140 mg/dL (more than or equal to 140) is taken as cut off for diagnosis of GDM.

[ii] Instrument used for diagnosis

For this programme, it has been decided that a plasma calibrated glucometer should be used for diagnosis of GDM instead of a semi auto- analyzer or auto-analyzer or any other testing methodology as it may lead to delay in getting the results immediately. Since it will be difficult for PW to come another day just to collect the result, testing facility with a glucometer should be available at all facilities in the ANC clinic itself. This facilitates getting the result immediately so that necessary advice may be given the same day.

A glucometer should also be available in the labor room for close monitoring of GDM cases during labor. Calibration of Glucometer recommended after 20 measurements using calibration test strips, provided with

glucometers.

Conclusion

Now we have got national guidelines to diagnose GDM, which has also been accepted by WHO and FIGO(Federation of International Gynaecology Obstetrics).

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There is only one way to avoid criticism: Do nothing, say nothing and be nothing.

— ARISTOTLE