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REVIEW ARTICLE

Make in India 'A Single Step Procedure' – To Diagnose Gestational Diabetes Mellitus is the Pride of the Nation

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Abstract

Single spot test regardless of meal, for detection of gestational Diabates Mellitus (GDM) is best for easy applicability, wide spread acceptance by patients and is cost effective even in rural community. A glucose solution of 75g anhydrous glucose in 300 ml water is given to the pregnant lady regardless of last meal. If 2 hour PPBs is 140-199mg/dl, it is diagnosed as GDM and if > 199mg/dl it is labeled as Pre GDM.

Keywords: ***GDM Diagnosis, Single spot test, DIPSI criteria***

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognised during pregnancy. The concern is GDM may play a crucial role in the increasing prevalence of diabetes and obesity. Further, women with a history of GDM are at an increased risk of developing future diabetes, predominantly of Type 2 DM and same is for their children-'intergenerational transmission of diabetes occurs.' This vicious cycle is a continuous process and thus GDM has become a public health issue,[1] necessitating universal screening for glucose intolerance in all pregnant women even if they have no symptoms.

All the diagnostic tests require women to be in the fasting state. Seldom, pregnant women come to the prenatal clinic in the fasting state. If they are asked to come on another day in the fasting state most of them do not turn up.[2] Even in the developed countries it was observed that the prenatal visit by pregnant women in the fasting state is impractical in many settings.[3] Hence it was decided to conduct a test to detect glucose intolerance without the women necessarily undergoing a test in the fasting state and it is preferable to perform the diagnostic test at the first visit itself.[3]

A prospective study was undertaken to elucidate a test procedure that would be rational to diagnose GDM irrespective of the last meal timing.[4] In this study it was observed '2 hr PG ≥ 140 mg/dl with 75 gm oral glucose administered to a pregnant woman in the fasting or non-fasting state, regardless of the last meal timing and was able to identify women with GDM.' Performing this test in the non-fasting state is rational, as glucose concentrations are affected little by the time since the last meal in a normal glucose tolerant woman, whereas it gets more affected in a woman with gestational diabetes.[5] 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,[6] her glycemic level increases with a meal and with glucose challenge, the glycemic excursion exaggerates further.[7] This cascading effect is advantageous as this would not result in false-positive diagnosis of GDM. This diagnostic procedure is recommended by Diabetes in Pregnancy Study Group India (DIPSI).

Advantages of the DIPSI procedure are:

- Pregnant women need not be in the fasting state.
- Causes least disturbance in a pregnant woman's routine activities.
- Serves as both screening and diagnostic procedure.

A couple of years after the publication of 'A single step procedure to diagnose GDM' in *Acta Diabetologia*, International Association of Diabetes and Pregnancy Study Group (IADPSG) published its recommendation based on the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study in *Diabetes Care* 2010.[8] 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 the 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 hours: 8.5 mmol/L (153 mg/dL) 7 with 75 g OGTT. Though one value is recommended to diagnose GDM this procedure requires 2 h OGTT, thus not cost effective.

IADPSG also suggests: fasting plasma glucose (FPG) >7.0 mmol/L (126 mg/dL)/A1C >6.5% in the early weeks of pregnancy if diagnostic of overt diabetes. Fasting >5.1 mmol/L and <7.0 mmol/L are diagnosed as GDM.[8] Interestingly, the recent publication does not recommend FPG in the early weeks of pregnancy.[9]

Disadvantages of the IADPSG suggestions are:

1. Attending the first prenatal visit in the fasting state is impractical in many settings.[8]
2. The dropout rate is very high when a pregnant woman is asked to come again for the glucose tolerance test.[8]

3. In all GDM, FPG values do not reflect the 2-hour post glucose with 75 g oral glucose; 2-hour plasma glucose (PG), is the hallmark of GDM.[10]
4. Center to center differences occurs in the detection of GDM frequency and relative diagnostic Importance of fasting, 1-hour and 2-hour glucose levels. This may impact the strategies used for the diagnosis of GDM.[11]
5. 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.[11]

At this juncture a publication came out with the following conclusions: (i) The DIPSI non-fasting OGTT criteria cannot be recommended for diagnosis of GDM due to its low sensitivity. (ii) Two-step procedure using the 50-g glucose challenge test as an initial screening test, followed by the diagnostic fasting OGTT, can be continued.[12] This conclusion needs introspection for the following reasons. DIPSI never suggested that the diagnostic test has to be done only in the non-fasting state. DIPSI recommends that the test procedure can be done in the fasting or non-fasting state irrespective of the last meal timing. As a matter of fact because of the practical problems a pregnant woman faces in attending the prenatal clinic in the fasting state, WHO recommends that the tests can be done in the non-fasting state too.[13] This does not mean that if a pregnant woman comes in the fasting state, she should be denied the test and asked to come again in the non-fasting state. In this context, WHO has made a few pertinent recommendations to diagnose GDM[13] refuting the publication.[12]

1. Most developing countries and health systems around the world do not have the capacity to implement a GDM detection programme based on all or only high risk women having a 2-h OGTT and therefore options which do not involve an OGTT are required.[13]
2. Access to health services is often limited and fasting may be problematic. Therefore, adherence to a request to attend the clinic fasting may be impractical and questionable in settings where the detection of hyperglycemia in pregnancy based on fasting values is low.[13]
3. A 2-step procedure requiring attendance on two separate occasions is often not feasible in many low and middle income countries.[13]
4. Laboratory glucose measurement is often not available and testing with a portable blood glucose meter is the only option.[13]
5. Randomized controlled trials showing the benefit of treating women with GDM included women who were identified primarily by ''post-load'' values. Therefore there is no high quality evidence that women, and their fetuses, benefit from treatment if only the fasting value is abnormal.[13]
6. Another point which should be noted in relation to FPG is the considerable variability between countries noted in the HAPO study with FPG diagnosing only 22% of GDM in women in Bangkok and Hong Kong compared with up to 71% in some US centres. A low diagnostic rate of FPG has also been reported in the Asian Indians with a fasting plasma glucose 5.1 mmol/l (92 mg/dl) diagnosing only 24% of GDM.[13]
7. Non-fasting plasma glucose testing: 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 non-fasting testing may be the only practical option.[13]

This single step DIPSI procedure which is a 'walk in test' is recommended by Ministry of Health Government of India. Besides WHO, International Federation of Gynaecologists and Obstetricians society (FIGO)[14] has also approved the DIPSI procedure of administrating 75 gm of oral glucose in the fasting or non-fasting state and diagnosing GDM if 2 h PG $\geq$ 140 mg/dl.

It is a matter of pride for Indians, as this is the only 'Make In India' guideline recognised by the international bodies.

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"Sometimes you put walls up not to keep people out, but to see who cares enough to break them down."

— Socrates