When are we Going to Settle the Diagnostic Criteria of Gestational Diabetes Mellitus?

Veeraswamy Seshiah1, Sidharth N Shah2, Vijayam Balaji3, C Anjalakshi4, Rajesh Jain5

Abstract

Guidelines to diagnose Gestational Diabetes Mellitus (GDM) have changed a number of times from O’Sullivan & Mahan, Carpenter & Coustan, World Health Organization, American Diabetes Association to that of International Association of Diabetes in Pregnancy Study Group (IADPSG). The IADPSG guideline was based on Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study which was performed in caucasian population only and thus literally cannot be considered as international. Recently a study commented that this guideline needs revision for standardization of this strategy for diagnosing GDM. Based on a prospective study, Diabetes in Pregnancy Study Group India (DIPSI) recommended a single step procedure of diagnosing GDM with 2hr PG > 140 mg/dl after 75g of oral glucose administered irrespective of the last meal timing. This guideline has been approved by the Ministry of Health Government of India, WHO, IDF and Federation of Gynaecologists and Obstetricians Society (FIGO). National Institute of Clinical Excellence (NICE) also recognises cut off value, 2hr PG > 140 mg/dl based on a study in multi ethnic population of UK. Hence, we can safely conclude, A Single Step procedure has settled the criteria for diagnosing GDM.

Introduction

Gestational Diabetes Mellitus (GDM) has been included in the classification of diabetes mellitus, yet there is no global uniformity in the guidelines to diagnose GDM. O’Sullivan first used the terminology gestational diabetes in 1961, following the term meta-gestational diabetes used by Dr Jp Hoet in 1954. Historically, initially the diagnostic criteria was suggested by O’Sullivan and Mahan followed by Carpenter and Couston.

Table 1: IADPSG Methodology to derive at the cumulative proportion of GDM

<table>
<thead>
<tr>
<th>N = 1463</th>
<th>Method - B</th>
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<tbody>
<tr>
<td>FPG ≥92 mg/dl</td>
<td>136</td>
</tr>
<tr>
<td>1h PG ≥180 mg/dl</td>
<td>65</td>
</tr>
<tr>
<td>2h PG ≥153 mg/dl</td>
<td>98</td>
</tr>
<tr>
<td>299</td>
<td>20.40%</td>
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Table 2: Prevalence of GDM not adhering to IADPSG methodology (OR= 1.75) and finally by International Association of Diabetes and Pregnancy Study Group (IADPSG)1 which was expected to settle the diagnostic issue. But recent observation of Annunziata Lapolla et al is that this procedure needs revision.2

IADPSG guidelines was accepted by many countries but not globally. WHO gave a lukewarm endorsement of the IADPSG criteria.3 WHO also made an observation that for a pregnant woman, the request to attend in 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.3 OGGT is resource intensive and many health services, especially in low resource settings, are not able to routinely perform an OGTT in pregnant women.3 In these circumstances, many health services do not test for hyperglycaemia in pregnancy.3 Therefore, options which do not involve an OGTT are required.3

Where is the problem and what is the problem for not universally accepting IADPSG guidelines?

In the city of Pasadena (USA) in 2008 a consensus meeting of IADPSG group was held. Most of the delegates voted for OR=1.75 for diagnosing GDM. A few countries including India opted for OR=1.5. Based on the Hyperglycaemia and adverse pregnancy outcome (HAPO) study performed in Caucasian population, IADPSG suggested that the diagnosis of GDM can be made when any of the following plasma glucose value meets or exceeds: 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) with 75 OGTT which corresponds to an OR =1.75. IADPSG methodology to derive cumulative prevalence of GDM is by measuring FPG alone, adding measurement of 1-hour plasma glucose identified additional prevalence and finally adding the 2-hour plasma glucose measurement.1

Table 4: Comparison between IADPSG and DIPSI criteria on GDM prevalence

<table>
<thead>
<tr>
<th>IADPSG and DIPSI Criteria</th>
<th>n = 1,463</th>
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<tbody>
<tr>
<td>Criteria</td>
<td>Prevalence of GDM</td>
</tr>
<tr>
<td>IADPSG (3 test – F, 1 hr and 2hr)</td>
<td>216 (14.6%)</td>
</tr>
<tr>
<td>DIPSI (1 test – 2 hr only)</td>
<td>196 (13.4%)</td>
</tr>
<tr>
<td>Difference</td>
<td>1.2%</td>
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</table>

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With this background, we analysed our data of 1463 pregnant women who underwent OGTT with 75g oral glucose. In this cohort the cumulative prevalence of GDM was 14.60% based on IADPSG methodology (Table 1).

Sacks et al mentioned that, centre to centre 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.4 If centres follow as observed by Sacks et al, the prevalence would vary depending on the centres which give importance to FPG, 1-hour or 2-hour and the cumulative prevalence will be 20.40% (Table 2). This anomaly could be the reason why in a recent publication, Annunziata Lapolla et al commented even at centres, that accepted IADPSG recommendation, the approach varies and needs revision for standardization of the strategy for diagnosing GDM.5 This is true, as many do not follow or may not be aware of the cumulative prevalence suggested by IADPSG.

The methodology of working out cumulative prevalence by applying OR=1.5 which few countries suggested during Pasadena meeting

IADPSG recommended that GDM can be diagnosed if any one value is abnormal in OGTT. This is possible only if OR=1.5 is implemented to diagnose GDM that is, FPG 90 mg/dl (5 mmol/l), 1-hour 160 mg/dl (8.8 mmol/l) or 2-hour 140 mg/dl (7.8 mmol/l) (Table 3).

A Single Step Procedure

Diabetes in Pregnancy Study Group India recommends a 2 hr PG ≥ 140 mg/dl (7.8 mmol/dl) with 75g oral glucose administered to a pregnant woman in the fasting or non-fasting state, irrespective of the last meal timing is able to identify women with GDM.6 Diagnosis of GDM with 2-hr PG ≥ 140 mg/dl (7.8 mmol/l) and treatment are worthwhile with a decreased macrosomia rate, fewer emergency caesarean section, serious perinatal morbidity and may also improve the women’s health-related quality of life.6

It is interesting, that properly worked out cumulative prevalence of GDM suggested by IADPSG procedure and DIPSI procedure is almost same with no statistically difference7 (Table 4).

Using the DIPSI criterion of 2-h PG ≥ 7.8 mmol/l, n = 196 (13.4%) women were diagnosed as GDM. By applying IADPSG recommendation the prevalence of GDM observed was n=214(14.6%). We found that there was no significant difference (P>0.05) in the discordant pair of diagnosing GDM by the two criteria which in turn implies, that the disagreement in diagnosing GDM by both criteria was not significant (P = 0.21).7

Yet another important observation was IADPSG criteria (2013 WHO criteria) and Non-fasting 75g OGTT, (DIPSI criteria) the performance was same6 (Figure 1).

Summary

The comparison of prevalence of GDM by IAPDSG and DIPSI procedures revealed no statistical difference provided proper methodology is applied. DIPSI criteria has been approved by the Ministry of Health Govt of India and International Societies, WHO, IDF and FIGO. DIPSI guideline is also being followed in South Asian counties.8,9 In relation to
FPG, there is a 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 centers. A low diagnostic rate of FPG has also been reported in the Asian Indians with a fasting plasma glucose 5.1 mmol/l diagnosing only 24% as GDM. 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. Hence DIPSI prefers 2-hour post glucose of 7.8 mmol/l to diagnose GDM.

Anunziata Lapolla et al observation mentioned earlier, that even at centers that accepted IADPSG recommendation, the approach varies and needs revision for standardization of the strategy for diagnosing GDM. Even if revised, the glycemic cut off to diagnose GDM in Caucasian women may not be suitable for other ethnic populations due to their anthropometric parameters.

Boyd Metzer et al suggested, in future clinical practice, simpler and more cost-effective strategies that do not require performing an OGTT on most pregnant women may be developed. DIPSI procedure fits in here. This procedure requires one blood sample drawn at 2hr after 75g oral glucose load for estimating plasma glucose. Even if the test is to be repeated in each trimester, the cost in performing this procedure will be 66% less than the cost of performing IADPSG recommended procedure.

GDM is an important public health problem at all levels of economic development, but immediate and pragmatic considerations, may limit the resources devoted to this issue in developing countries. Thus, DIPSI procedure is feasible, sustainable, evidence based cost-effective and high impact best buy for less resource settings at present. We hasten to add as stated by David Macintyre that for GDM diagnosis, “one size does not fit all.” where possible, diagnostic thresholds should be adapted using local data.

References


