

Original Research Article

DIABETES IN PREGNANCY STUDY GROUP IN INDIA (DIPSI) – A NOVEL CRITERION TO DIAGNOSE GDM

ABSTRACT

Background: Most of the people in India reside in rural areas. Universal screening in such settings requires a simple economical test like Diabetes in Pregnancy Study Group in India (DIPSI). In this context, DIPSI procedure of estimating plasma glucose from one blood sample is cost effective and evidence based as revealed by the pregnancy outcome.

Aim: To compare WHO and DIPSI CRITERIA in diagnosing GDM.

Materials and methods: 149 pregnant women attending antenatal clinic of Santhiram General Hospital were selected. OGTT was performed in them according to WHO criteria by taking two samples fasting and 2 hr. After 2-3 days patients were asked to undergo GTT according to DIPSI. *“DIPSI is a one step procedure with a single glycemic value.”*

Statistical analysis: The mean and S.D of age and parity were calculated. Comparison of diagnosis of GDM by WHO and DIPSI were analyzed by Fischer exact test (chi- square test) using Statistical analysis was performed using SPSS software (version 20) and MedCalc (version 12.7.0).

Results: Out of 149 pregnant women who underwent screening for GDM, 63 were diagnosed to have GDM. The mean age and S.D of pregnant women were 24.35 ± 4.77 years. The mean glucose values and S.D of GDM cases is 154.32 ± 8.7 . 52 women were diagnosed as GDM by both WHO and DIPSI. WHO identified 63 cases and DIPSI 58 cases i.e. 92% of cases identified by WHO were found to be identified by DIPSI. We compared both tests for their significance by Fischer exact test, Chi squared equals to 75.181($P < 0.0001$) which is extremely significant.

Conclusion: DIPSI has all that qualities of a screening test. It is simple, single, convenient, economical, can be used as both diagnostic as well as screening test, and with good perinatal outcome. So can be used in routine laboratory to diagnose GDM.

KEY WORDS: gestational diabetes mellitus (GDM), world health organization (WHO), diabetes in pregnancy study group in India (DIPSI), impaired glucose tolerance (IGT).

32 INTRODUCTION

33 Gestational Diabetes Mellitus (GDM) is defined as glucose intolerance first recognized
 34 during pregnancy. The recent data on the prevalence of GDM in our country was 16.55% by
 35 WHO criteria of 2 hr PG $\geq$ 140 mg/dl. ⁽¹⁾ The maternal and fetal outcomes depend on proper
 36 screening of high risk patients. The conventional methods like WHO and IADPSG So far we
 37 are using to diagnose GDM are confusing, contradictory and country specific guidelines. To
 38 avoid this DIPSI was set to the Indian standards, simple, convenient and can be used as a
 39 universal screening test. ⁽¹⁻³⁾ Our aim of the study is to compare WHO and DIPSI CRITERIA
 40 in diagnosing GDM.

41 MATERIALS AND METHODS

42 The present study was a prospective cross sectional study done among 149 pregnant women
 43 irrespective of age, parity attending for routine antenatal checkup in the department of
 44 gynaecology and obstetrics, Santhiram general hospital. Ethical clearance was taken.
 45 Informed consent was taken from all women. Women known to have pre-existing diabetes
 46 were excluded from the study.

47 All these were screened during gestational period between 24 weeks to 28 weeks. We
 48 performed Oral Glucose Tolerance Test (OGTT) by giving 75 grams of dextro glucose.
 49 According to WHO criteria with two venous blood samples fasting and 2 hours were
 50 collected. After 2-3 days patients were asked to undergo 75grams GTT without fasting,
 51 irrespective of time of meals and single 2 hours blood sample is collected. Simultaneous
 52 urine samples are also collected. All venous blood samples were analyzed for plasma
 53 glucose levels by GOD –POD method on semi automated analyzer.

54 STATISTICAL ANALYSIS

55 WHO criteria and DIPSI were compared to diagnose GDM. According to WHO guidelines,
 56 any one criterion can be used to diagnose GDM fasting $\geq$ 126 mg/dl (7.0mmol/l) or 2-hr value
 57 $\geq$ 140 mg/dl (7.8 mmol/l) (3.4). According to DIPSI criteria irrespective of meals and time 2-
 58 hours value $\geq$ 140 mg/dl a single step, nonfasting procedure.

59 The mean and S.D of age and parity were calculated. Comparision of diagnosis of GDM by
 60 WHO and DIPSI were analyzed by Fischer exact test (chi- square test) using Statistical
 61 analysis was performed using SPSS software (version 20) and MedCalc (version 12.7.0).

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63 RESULTS

64 Out of 149 pregnant women who underwent screening for GDM, 63 were diagnosed to have
65 GDM. The mean age and S.D of pregnant women were 24.35 ± 4.77 years. Of them 126 were
66 primi and 23 were multipara. The mean glucose values and S.D of GDM cases is $154.32 \pm$
67 $8.7. 52$ women were diagnosed as GDM by both WHO and DIPSI

68 **Table1:** Shows the comparision between the existing guidelines. In our lab we are following
69 WHO 75g criteria.

70 **Table-1** Diagnostic criteria
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criteria	Sample	f/non f	Glucose load	Fasting mg/dl	1hr mg/dl	2hr mg/dl	3hr mg/dl
ADA	F,1hr,2hr, 3hr	Fasting	100gm	> 95	> 180	> 155	>140
WHO	F, 2hr	Fasting	75 gm	>126	-	>140	-
IADPSG	F,1hr,2hr	Fasting	75gm	>92	> 180	>153	-
DIPSI	2hr	Irrespective of time and meals	75 gm	-	-	>140	-

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73 **Table2:** Shows the number of cases diagnosed by WHO Criteria. 63 cases were screened by
74 WHO out of which 6 cases were diagnosed by 1st hr sample and rest 57 cases by 2nd hr
75 sample.

76 By applying DIPSI to the same 63 GDM cases, 58 cases were diagnosed to have GDM. This
77 shows that DIPSI was found to identify 58/63 (92.06%) of GDM cases identified by WHO.
78 If we consider the 2nd hr samples out of 57 cases of WHO, 58 cases of DIPSI identified GDM
79 (57/58) almost 98.27% cases could be screened by DIPSI. if we carefully observe the 1st hr
80 sample normal range (126mg/dl) it is diabetes range outside the pregnancy but not IGT or
81 GDM. The reason for those 6 cases diagnosed by 1st hr seems to be over diagnosed by WHO
82 criteria.

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Table: 2 Distribution of cases in WHO and DIPSI criteria

DIAGNOSTIC CRITERIAE	1 st hr	2 nd hr
WHO n=63	6cases	57cases

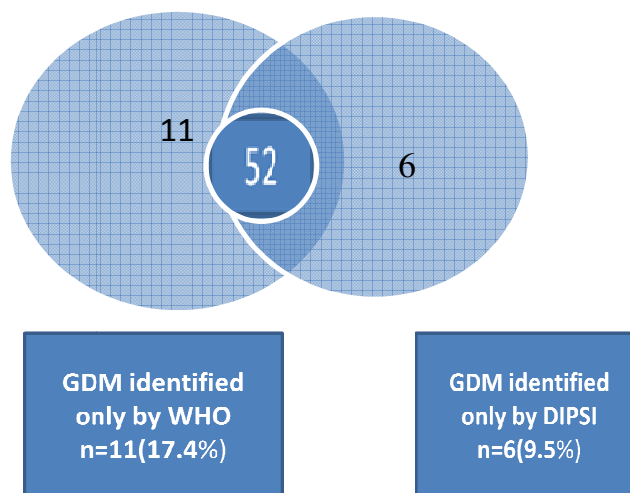
DIPSI n=58	-	58cases
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Table 3: Shows the comparison of two diagnostic tests. When both criteria were applied 52 cases were diagnosed, 11 cases were diagnosed only by WHO criteria, 6 cases were identified only by DIPSI criteria, and 80 cases were GDM negative by both. Fischer exact test (chi square) is applied to analyze the significance of both tests. P-value is extremely statistically significant. 92% of cases identified by WHO were also found by DIPSI. This shows DIPSI can be used not only as a screening test but also as a diagnostic procedure.

Table: 3 Fischer's exact test

WHO	DIPSI POSITIVE	DIPSI NEGATIVE	Total
POSITIVE	52	11	63
NEGATIVE	6	80	86

Figure 1: Venn diagram



However, as shown in the Venn diagram only 52 women of the total 63 women with GDM (92%) were identified by both DIPSI and WHO criteria. Thus, 11/63 (17.4%) of the GDM women would have been missed if DIPSI criteria alone were used. Conversely, 6/63 (9.5%) of the GDM women would have been missed if WHO criteria alone was used. Chi square equals to 75.181 with 1 degrees of freedom. The two tailed p-value is < 0.0001. The association between rows and columns is considered to be extremely statistically significant.

DISCUSSION

Normal pregnancy is characterized by “facilitated insulin action” during 1st half of pregnancy and “diabetogenic stress” in the 2nd half of pregnancy. These changes are a result of high hormone levels (elevation of progesterone, oestriol, oestradiol, oestrone and HCS), decreased glucose disposal rate, increased fasting serum insulin levels, and decreased insulin secretion after meals.⁽⁵⁾ A pregnant woman who is not capable of increasing her insulin levels against the developed insulin resistance land up in GDM.

We are more concerned about GDM as two generations are at risk. One is the women with history of GDM may become future diabetic and also their children. Another is perinatal morbidity and mortality.⁽⁶⁾

With the alarm of rising tide of GDM it has become mandatory to set criteria of our own that meet our standards of Indian population to screen high risk people.^(7, 8) All other conventional diagnostic criteria like WHO criteria, IADSPG are confusing, cumbersome to the patient and are set according to their population. Another disadvantage is they do not give any information about perinatal outcome and meant to screen only high risk population. To avoid this, modified WHO criteria or DIPSI is introduced to diagnose and to screen GDM.

“ DIPSI is a one step procedure with a single glycemic value” In the antenatal clinic, a pregnant woman after undergoing preliminary clinical examination is given a 75 g oral glucose load, irrespective of whether she is in the fasting or non fasting state, 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 plasma glucose is $\geq$ 140 mg/ dl.^(9,10)

DIPSI is used as a universal screening test. By following the usual recommendation screening is done between 24 and 28 weeks of gestation, early screening in the first trimester is suggested if the 2hr PG > 200mg/dl. The recent concept is to screen for glucose intolerance in the first trimester itself as the fetal beta cell recognizes and responds to maternal glycemic level as early as 16th week of gestation. If found negative at this time, the screening test is to be performed again around 24th – 28th week and finally around 32nd – 34th week.^(10,11)

Our study shows 92% cases identified by WHO has also been screened by DIPSI. This is in accordance with the study done by Sivagnanam Nallaperumal etal where 98% of cases were picked up by DIPSI.⁽¹²⁾ If we consider the 2nd hr samples out of 57 cases of WHO criteria, 58 cases of DIPSI identified GDM (57/58) almost 98.27% cases could be screened by DIPSI. The difference seen may be because of the inherent contradiction that exists in the normal

range of 1st hr sample in WHO >126 mg/dl which is used to diagnose diabetes outside pregnancy, where as GDM is IGT outside pregnancy. Wahi et al. observed in their randomized controlled study, the advantage of adhering to a cut-off level of 2-hour PG $\geq$ 7.8 mmol/L in diagnosis and management of GDM for a significantly positive effect on pregnancy outcomes both in relation to mother as well the child. Perucchini et al. also suggest one-step diagnostic procedure (2-hour PG $\geq$ 7.8 mmol/L) to diagnose GDM. Franks et al. documented that when maternal 2-hour PG was $\geq$ 7.8 mmol/L, the cumulative risk of offspring developing type 2 DM was 30% at the age 24 years. ^(13, 14, 15)

The notion that GTT should be performed in fasting state is swipped away by DIPSI as 2hr values of both criteria is same (>140mg/dl) .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, her glycemic level increases with a meal and with glucose challenge, the glycemic excursion exaggerates further.

CONCLUSION

Traditional WHO requires fasting and is inconvenient to the patient whereas DIPSI, a nonfasting single step procedure has the same sensitivity and specificity in diagnosing and screening GDM. Thus, DIPSI procedure would serve as novel criteria to diagnose GDM.

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