

Evaluation of “Diabetes in Pregnancy Study Group of India” (DIPSI) Criterion as a Diagnostic Test for Gestational Diabetes Mellitus

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ABSTRACT

Introduction: In view of the alarmingly increasing incidence of Gestational Diabetes Mellitus (GDM), worldwide, as well as in India, a consensus to bring about standardization for diagnosis of GDM is needed. Internationally, the WHO 2013 criteria is being widely used, while (Diabetes In Pregnancy Study Group of India) DIPSI non fasting criteria is popularly used in India. There still remains many missed cases of GDM in India, which is a cause of concern. This study was done to compare the DIPSI non fasting, with WHO 2013 criteria for diagnosis of GDM.

Methods: this cross-sectional study included 530 pregnant women, attending antenatal clinic of a tertiary care center, of North India, from Feb. 2018 to March 2019 and fulfilling inclusion criteria. All women attending antenatal clinic, during the study period, were subjected to capillary glucose evaluation, 2 hours after 75g oral glucose load, irrespective of the timing of last meal (DIPSI), as part of routine antenatal checkup. After 7 days, only those 530 women, who turned up in fasting state, and fulfilled inclusion criteria, were enrolled in the study and subjected to fasting 75g, oral glucose tolerance test (OGTT) (WHO 2013). Accuracy of DIPSI test was compared, to the fasting WHO 2013 criteria. Capillary glucose was measured using regular, well calibrated, point of care, “Optium Free Style” glucometer.

Results: Out of 107 women diagnosed to have GDM by WHO 2013 criteria, only 89 were diagnosed by the DIPSI criteria. DIPSI had a low sensitivity (83.18%) when compared to the WHO 2013 criteria,

Conclusion: This study showed that when non fasting DIPSI criteria was used as diagnostic criteria, 10.58% women with GDM, missed the diagnosis. Considering the adverse maternal and perinatal outcome of GDM, implication of missed diagnosis would be grave, especially in a developing country, like India. Hence, use of DIPSI criteria for diagnosing GDM should be reconsidered.

Key words: GDM, DIPSI, OGTT, Diabetes in Pregnancy.

INTRODUCTION

The prevalence of Gestational diabetes mellitus (GDM), that is diabetes diagnosed during pregnancy, is increasing alarmingly in India. It is estimated that about 4 million pregnant women are affected with GDM in India, at any given time point.¹

GDM is the most common metabolic disorder of pregnancy and is associated with increased maternal, fetal and neonatal morbidity and mortality.² The repercussion of diabetes in pregnancy, is not only on the current generation but also on the next generation. Evidences suggest that infants of mothers with diabetes in pregnancy are at

increased risk of obesity, diabetes, hypertension and T2DM, later in life. Mothers, with history of GDM are at increased risk of T2DM and cardiovascular disease.^{3,4,5} Keeping in view, the rising trend, if cases of GDM are missed, our coming generation would be crippled with diabetes and metabolic syndrome and would constitute a population with suboptimal health and poor productivity.

Screening and early diagnosis of diabetes in pregnancy, may prevent or reduce both immediate and long-term harm, to mother and baby.⁶

Hence, this disease should be given utmost priority and rigorous research for a sensitive screening modality and its uniform and universal implementation should be initiated.

Unfortunately, in India, despite increase in antenatal care and institutional deliveries, there still remains many missed cases of GDM, amounting to a great harm to public health in our country.

After the establishment of DIPSI criteria as non-fasting screening test for GDM, it is being widely used in India, for the sake of simplicity and better compliance.⁷ This criterion is considered appropriate for a developing country like India, because of uncertainty of follow up visits due to lack of awareness and illiteracy still prevailing at large in our country.

Internationally, the WHO 2013 criteria, of fasting oral glucose tolerance test (OGTT), is used to diagnose GDM and is considered gold standard.⁸

Many studies from different parts of our country have shown poor sensitivity of DIPSI for diagnosis of GDM.

This study was aimed at evaluating the sensitivity of DIPSI criteria in

comparison to the internationally accepted WHO 2013 criteria for diagnosis of GDM.

MATERIAL AND METHODS

This cross-sectional observational study included 530 pregnant women, attending antenatal OPD of a tertiary care center of North India. Pregnant women attending antenatal OPD, from Feb. 2018 to March 2019 underwent capillary glucose evaluation, 2 hours after 75g oral glucose load, irrespective of their timing of last meal, as part of routine antenatal checkup. They were called after an overnight fast of at least 8 hours, after 7 days, for their next visit. 530 Pregnant women fulfilling inclusion criteria and giving consent and who turned up in fasting state, were subjected to 1 hour and 2-hour oral 75g glucose, capillary glucose evaluation, according to the WHO 2013 criteria. Detailed history and physical examination were performed and BMI was calculated according to pre pregnancy or first trimester weight. All procedures followed were in accordance with the ethical standards.

Accuracy of DIPSI was compared with fasting 75g OGTT, using cut offs, as per the 2013 WHO criteria, for diagnosis of GDM. Capillary glucose was measured using regular, well calibrated, point of care, “Optium Freestyle” glucometer, in the antenatal OPD.

Known diabetics, critically ill pregnant women, pregnant women taking medications affecting glycemic control (steroids, beta mimetics etc.) were excluded from the study.

For comparison between groups, Pearson’s Chi Square test was used. A p-value of < 0.05 was set as the significance threshold.

RESULTS

Table 1: Patient characteristics of GDM positive patients

Patient Characteristics	Total = 530	GDM positive (n= 107)		Chi square	P value
		DIPSI positive (n= 89)	WHO (2013) positive (n= 107)		
Age (years)					
18-24	159 (30%)	35 (39.3%)	42 (39.3%)		
25-34	275 (51.9%)	51 (57.3%)	62 (57.9%)	0.0546	.973
≥ 35	96 (18.1%)	03 (3.4%)	03 (2.8%)		

Table 1 : Continued...

Gestational age (weeks)					
≤ 12	126 (23.8%)	04 (4.5%)	07 (6.5%)		
13-26	195 (36.8%)	28 (31.5%)	34 (31.8%)	0.4077	.8155
27-40	219 (41.3%)	57 (64.0%)	66 (74.1%)		
BMI (kg/m²)					
18.5 – 24.9	335 (63.2%)	38 (42.7%)	39 (36.4%)		
25 – 29.9	138 (26.0%)	49 (55.1%)	63 (58.9%)	1.407	.494
30 – 34.9	57 (10.8%)	02 (2.2%)	05 (4.7%)		

Table 2: Cross analysis of diagnostic capability of DIPSI with WHO 2013 criteria

GDM as diagnosed by WHO 2013 criterion	DIPSI test result	
	Positive	Negative
Positive (n=107)	89 (83.18%)	18 (16.82%)
Negative (n= 423)	0	423 (100%)
Total = 530	89 (16.79%)	441 (83.21%)

Table 3: Statistical parameter of DIPSI with WHO 2013 criteria.

Statistical parameter	Value
Sensitivity	83.18%
Specificity	100%
Positive predictive value	100%
Negative predictive value	96.07%

DISCUSSION

A total of 530 pregnant women, who were successfully followed up, were included in the study. 107 women (20.18%) were diagnosed to have GDM by the 2013 WHO criteria, while only 89 women (16.79%) were diagnosed to have GDM by DIPSI criteria.

The DIPSI non-fasting 75g, 2 hours cut off of 140 mg/dl, had a low sensitivity of 83.18%, when compared to the 2013 WHO criteria. 18 pregnant women (16.82%) with GDM, missed diagnosis by DIPSI criteria. These missed cases were falsely labelled as normal, probably because, the test did not account for fasting hyperglycemia. All pregnant women diagnosed with non-fasting DIPSI criteria were also diagnosed as GDM with fasting 2013 WHO criteria. Thus, DIPSI had 100% positive predictive value. However, its negative predictive value was poor (96.07%).

Considering the prevalence of 5 million GDM cases per year in our country,⁹ this would translate into approximately 8 lakhs and 41 thousand missed GDM cases per year, which is a huge number to be ignored.

There is high quality evidence indicating that, early diagnosis and treatment of GDM statistically significantly reduces the relative risk of adverse outcome

in both, the mother and the baby.¹⁰ Missing the diagnosis would have grave consequences over two successive generations.

Many comparative studies from different parts of our country have shown poor sensitivity of the DIPSI criterion.¹¹ In the largest study till date, in urban and rural Tamil Nadu, as part of Indian Diabetes Federation sponsored WINGS program, DIPSI was found to have poor sensitivity of 27.7% when compared to the WHO 1999 criteria and 22.6% when compared to the (International Association of Diabetes and Pregnancy study Groups) IADPG criteria.¹²

Another study from New Delhi, showed that 22.36% GDM women missed the diagnosis when DIPSI criteria was used.¹³ However, a few studies have shown higher sensitivity of DIPSI.^{14,15}

In a study by Ghada M et al in Egypt, sensitivity and specificity of DIPSI was 100% and 98.5% respectively, as compared to IADPG. But positive predictive value was only 83% and negative predictive value was 100%. The author predicted that higher sensitivity of DIPSI may be due to the diurnal variation in insulin level, glucose tolerance and beta cell responsiveness, taking into consideration that DIPSI could be performed at any time in the day while WHO test could be done in the morning.¹⁶

DIPSI is being widely used in India, for screening and diagnosis of GDM, for the sake of ease and better compliance. In recent years, India has been successful in reaching health care facility to rural and remote areas, through primary health care centers and sub centers and through mobile medical units. If the test facility is made available to the smallest and the most remote health care facilities, getting pregnant women in fasting state or testing

made available to their doorsteps, would not be a great challenge.

The evidence base of DIPSI criteria is a single center study, comparing non-fasting OGTT with the WHO 1999 criteria, showing 100% sensitivity and specificity.¹⁷

Hyperglycemia and adverse pregnancy outcome (HAPO) derived and IADPG consensus panel formulated, diagnostic criteria, has been adopted and endorsed by the WHO in 2013. This criterion for GDM diagnosis is based, not on the diagnostic accuracy, but on the prognostic accuracy, as derived from the HAPO study based, risk of adverse neonatal outcome. The IADPG consensus panel, decided the diagnostic threshold for fasting, 1 hour and 2 hours plasma glucose concentration, at which the key pregnancy outcomes, i.e., birth weight >90th percentile, cord C Peptide >90th percentile and neonatal percent body fat >90th percentile, are increased 1.75 folds over the mean HAPO study population. Adjustments were also made for race and ethnic groups, parity, age, BMI, smoking and alcohol use, presence or absence of family history of diabetes etc.

Large outcome-based studies comparing DIPSI with WHO criteria is needed.

CONCLUSIONS

WHO in 2013, adopted the IADPG criteria, for diagnosis of GDM, because this is the only outcome-based criteria and has the ability to diagnose and treat GDM earlier, thereby reducing maternal, fetal and neonatal complications. DIPSI is easy and simple, but has lower sensitivity as compared to the WHO 2013 criterion and implementing the WHO criterion universally in India, should be considered.

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