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Original Research Article

Relevance of fasting plasma glucose for diagnosing gestational diabetes mellitus

Kalpana Singh[*1], Bhawna Mahajan[2], Neha Srivastava[3] and Nisha Singh[4]

[1]*Associate Professor, Department of Biochemistry, King George's Medical University, Lucknow, India*
[2]*Associate Professor, Department of Biochemistry, GB Pant Institute of Post Graduate Medical Education and Research, New Delhi, India*
[3]*Junior Research Assistant, Department of Biochemistry, King George's Medical University, Lucknow, India*
[4]*Professor, Department of Obstetrics & Gynecology, King George's Medical University, Lucknow, India*

Abstract

Introduction: Gestational diabetes mellitus (GDM) is defined as the raised plasma glucose level detected first during pregnancy. A simple blood sugar test can detect gestational diabetes and to interpret the value various criteria's are available like ADA (2016), ACOG, *WHO* and IADPSG each one having its own limitations. In 2009, DIPSI was proposed for diagnosing/ screening GDM which was later approved by MoH, *GOI*.
Objective: To estimate fasting and 2hr post prandial plasma glucose level following 75gm glucose load in diagnosing gestational diabetes mellitus and to find out the correlation between fasting and 2hr post prandial values in GDM women.
Material and method: As per inclusion/exclusion criteria of the study 200 pregnant females attending the antenatal clinic were enrolled. Fasting and 2hr post prandial plasma glucose samples were collected following 75gm anhydrous glucose for plasma glucose estimation in fluoride vaccutainer under aseptic precautions. Plasma glucose was analyzed by enzymatic method on fully autoanalyzer. For diagnosing gestational diabetes *WHO 1999 criteria* were taken.
Results: Out of 200 pregnant females, 70 females were included in our study, 52 were healthy while 18 were diagnosed as GDM according to *WHO* criteria. No correlation was observed between fasting and 2hr post prandial plasma glucose.
Conclusion: Fasting plasma glucose sample can be excluded for screening GDM hence, 2hr PP following 75gm glucose load as suggested in one step DIPSI criteria can be used an alternative method for diagnosis of GDM because it is convenient and cost-effective.

Keywords: Gestational diabetes mellitus, DIPSI, WHO 1999, universal screening

***Correspondence Info:**
Dr. Kalpana Singh
Associate Professor,
Department of Biochemistry,
King George's Medical University,
Lucknow, U.P India

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1. Introduction

Gestational diabetes mellitus (GDM) also known as pregnancy induced diabetes mellitus is defined as the glucose intolerance of variable severity with onset or first recognition during pregnancy [1]. In 2015, IDF *(International Diabetes Federation*) reported that 16.2% of live birth to women had some form of hyperglycemia in pregnancy and 85.1% were due to GDM [2]. Southeast Asian population is at 11 fold higher risk of developing GDM [3]. In 2015, Mithal *et al* reported prevalence of GDM varied from 3.8% - 41% in different cities of India [4]. This wide range in prevalence in their study may be due to variation in diagnostic criteria used for diagnosing GDM. In 2016, Mahalakhsmi *et al* in their study observed that in India 36.7% of the physicians used one step DIPSI (Diabetes in Pregnancy Group India), 24.7% opted *WHO 1999* (*World Health Organization*), 23.8% by IADPSG (International Association of Diabetes and Pregnancy Study Group) while only 14.8% were diagnosed by ADA (American Diabetes Association) criteria [5]. Though DIPSI was commonest among physician but actually only 12.7% used it with proposed series of step. Prompt diagnosis of GDM is crucial as two generations are at risk of developing diabetes mellitus in future. Diabetes in

pregnancy is associated with increased risk of congenital malformation, still birth, macrosomia, perinatal mortality and pre-eclampsia [6,7]. The baby of GDM mother is at life-long increased risk of glucose intolerance, obesity and metabolic syndrome [8].

As population of India is at higher risk of developing GDM, its screening and diagnosis plays a crucial role to decrease maternal and fetal mortality. Universal screening should be applied to the whole obstetric population [9] rather than targeting the high risk group [10] between 24 – 28 weeks of gestation. *WHO 1999* criteria proposed cut off value of ≥126mg/dl and ≥140mg/dl for fasting and 2hr post prandial (75gm anhydrous glucose) respectively for diagnosing GDM [11]. A single step procedure was developed by Diabetes in Pregnancy Study Group India (DIPSI), which was approved by Ministry of Health, Government of India and also recommended by *WHO* [12,13]. Single value of 2hr PP ≥140mg/dl following 75gm glucose dissolved in 300ml of water (fasting/non-fasting state) is sufficient to diagnose GDM by DIPSI criteria. DIPSI is simple, feasible, cost-effective and also most of the time pregnant women do not come in fasting state hence, the dropout rate is very high when pregnant women is asked to come again in fasting state.

In our study we would like to find out the importance of fasting plasma glucose used in all the criteria except DIPSI for diagnosing GDM. We hypothesize that if fasting plasma glucose levels are within the normal range in pregnant women, there is no need to collect fasting sample as suggested by DIPSI also. One sample of 2hr PP after 75gm of glucose load irrespective of fasting status may be more practical approach for efficiently screening and diagnosing GDM.

2. Material and method

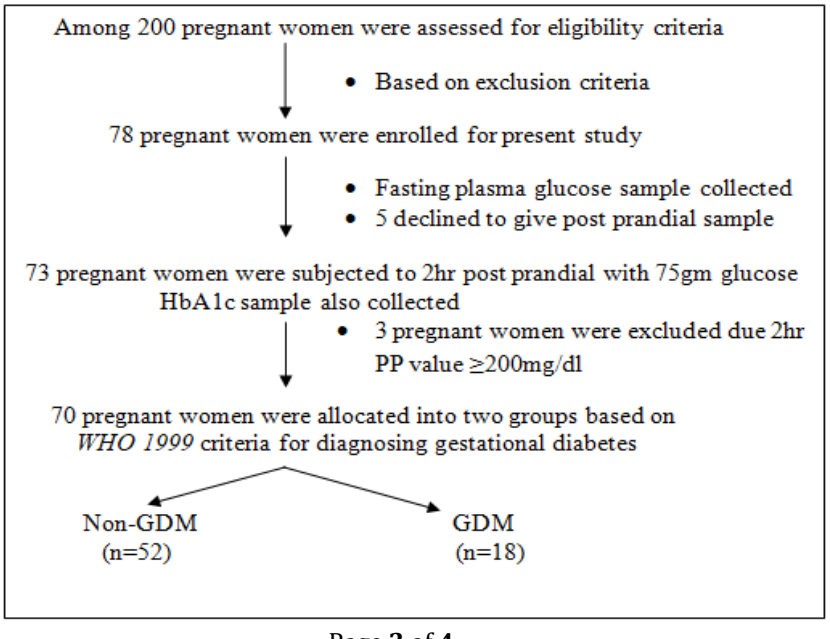
Study was conducted in the Department of Biochemistry, King George's Medical University, Lucknow in collaboration with Department of Obstetrics and Gynaecology, King George's Medical University, Lucknow. 200 Pregnant women were enrolled from Antenatal Clinic of Queen Mary Hospital, KGMU, Lucknow over a period of 6 months from Feb 2017 – July 2017. Ethical clearance was taken from Institutional Ethical Committee. Pregnant women with previous history of Type 1 or 2 diabetes mellitus or gestational diabetes mellitus, HbA1c (glycated haemoglobin) ≥6.0%, 2hr post prandial ≥200mg, and any other history of chronic illness were excluded from the study.

2.1 Allocation of pregnant women into two groups: 200 pregnant females were assessed for eligibility out of which 78 were enrolled in the study. Out of 78 pregnant women 5 declined to give post prandial sample, 3 post prandial samples was ≥200mg/dl as shown in Fig.1.

2.2 Blood sample collection and estimation: Fasting plasma glucose was collected in 78 women out of whom 5 refused to give post prandial sample. 73 women were subjected to 75gm anhydrous glucose in 300ml water and after 2hr post prandial samples were collected along with HbA1c sample. Samples for plasma glucose estimation were collected in fluoride vaccutainer and HbA1c sample was collected in ETDA vaccutainer. In 3 women post prandial values were ≥200mg/dl hence excluded from the study. Plasma glucose was estimated by Glucose oxidase, hydrogen Peroxide (Trinder) method of Q-line kit on ELITech Selectra while HbA1c was estimated by HPLC method on Biorad D10.

2.3 Categorization of 70 pregnant women into two groups: Based on *WHO* 1999 criteria 70 pregnant women were categorized into non-GDM (n=52) and GDM (n=18).

Figure 1: Flowchart for selection of study group



3. Results

In present study out of 70 women, 52 (74.3%) were healthy pregnant women (non-GDM) while 18 (25.7%) were GDM based on *WHO 1999* criteria. Out of 25.7% GDM women 11.1%, 61.2% and 27.7% were from 1st, 2nd and 3rd trimester of pregnancy. No difference was observed in mean HbA1c value of non-GDM (4.99 ± 0.398%) and GDM (4.83 ± 0.339) women. Mean fasting plasma glucose level in non-GDM group was 79.15 ± 10.29mg/dl and in GDM group was 86.94 ± 14.52mg/dl. Though statistically significant difference was observed in the fasting plasma glucose level of non-GDM and GDM women but the mean values were below the cut-off used in *WHO* criteria for diagnosing GDM i.e. <126mg/dl as shown in table 1. Mean of 2hr PP was 107.93 ± 15.74mg/dl in non-GDM and 146.83 ± 10.95mg/dl in GDM women which was statistically significant (p value 0.0001) as shown in table 1. Unpaired t-test was used to compare 2hrPP plasma glucose level in non-GDM and GDM women which was statistically significant as shown in table 2. No significant correlation was observed between fasting and 2hr PP plasma glucose level in GDM (table 3).

Table 1: Mean Fasting Plasma Glucose and 2hr Post Prandial in Non-GDM and GDM women

	Plasma glucose level (mg/dl)	
Study group	**Fasting (Mean ± SD)**	**2hrPP (Mean ± SD)**
Non-GDM (52)	79.15 ± 10.29	107.93 ± 15.74
GDM (18)	86.94 ± 14.52	146.83 ± 10.95
P value	0.016*	0.0001*

Table 2: Correlation between fasting and 2hr PP plasma glucose in GDM women

		FBS	PP
Fasting Blood Sugar (FBS)	Pearson Correlation	1	0.216
	Sig. (2-tailed)		0.389
	N	18	18
Postprandial (PP)	Pearson Correlation	0.216	1
	Sig. (2-tailed)	0.389	
	N	18	18

4. Discussion

In our study we observed that incidence of GDM was 25.7% with *WHO 1999* criteria. Polur *et al* observed incidence of 42.2% with *WHO 1999* criteria in a study conducted in 149 pregnant women of Andhra Pradesh, India [14]. While Mohan V *et al* reported incidence of 8% with *WHO 1999* criteria in study of 1400 pregnant women of Tamil Nadu [15]. Similarly with DIPSI criteria incidence of GDM was reported as 4.2% [15], 6.52% [16], 38.9% [14], 8% [17] and 8.7% [18] among the population southern region of India.

This variation in incidence of gestation diabetes mellitus can be observed which may be genetic or geographical for which we need study from all the states of India using one diagnostic criterion. Among 52 healthy pregnant women (non-GDM) mean fasting plasma glucose was 79.15 ±10.29 mg/dl (range: 68.86 – 89.44 mg/dl) and in 18 women with gestational diabetes mellitus was 86.94 ±14.52 mg/dl (range: 72.44 – 101.46 mg/dl). Though the fasting plasma glucose was significantly higher (p value 0.016) in GDM women as compared to healthy pregnant women but in both the groups range of fasting levels were below the cut-off used for diagnosing GDM according to *WHO* 1999 criteria i.e., <126 mg/dl. Mean 2hr post prandial plasma glucose was 146.83 ± 10.95 mg/dl in GDM women which was significantly higher as compared to non-GDM women 107.93 ± 15.74 mg/dl (p value 0.0001).

Mohan V *et al* in their study compared OGTT (oral glucose tolerance test) in fasting and random state and concluded that DIPSI has low sensitivity when compared to *WHO 1999* [15]. They also emphasized that in country like India dropout rate for OGTT is high as observed in their study (21.48%) and advised single step 75gm OGTT with IADPSG criteria. While Polur H *et al* compared *WHO 1999* with DIPSI and observed incidence of 42.2% and 38.9% respectively [14]. In their study by using *WHO 1999* criteria 6 women were diagnosed as GDM on the basis of fasting plasma glucose sample. In our study conducted on 70 apparently healthy women, 18 were diagnosed as GDM on the basis of 2hr PP value as fasting plasma glucose level was within normal limit.

According to *WHO 1999* criteria 2hr PP cut-off for diagnosing GDM is ≥140 mg/dl and same cut-off was proposed by DIPSI criteria. In DIPSI one sample is required i.e 2hr PP after 75gm anhydrous glucose load, which is convenient and cost-effective as compared to other methods as recommended by Seshiah *et al* [19]. Also pregnant women need not to be in the fasting state for screening GDM which will decrease the drop-out rate which is higher in developing countries. While on the other side Mohan *et al* [15] and Pulkit *et al* [20] criticized the use of DIPSI criteria because of low sensitivity and under diagnosis. In our study also we observed that fasting plasma glucose levels were within the normal range in both GDM and non-GDM group as shown in table 1. Furthermore we observed that no correlation was found between fasting and 2hr PP plasma glucose level among pregnant women with gestational diabetes mellitus. Hence, we propose that fasting sample can be omitted for screening GDM as also suggested by DIPSI. For screening all the pregnant women for GDM in every trimester we need a convenient, worthwhile, viable and versatile criterion so that fetal and maternal mortality can be reduced in future. This observation is well supported with the findings of Mahalakshmi MM *et al* [5] that approximately 50% of the doctors in India do not follow any guidelines recommended for screening or diagnosing GDM.

5. Conclusion

In developing countries like India, we need a cost effective test for screening of gestational diabetes mellitus. DIPSI guidelines provide a convenient, simple, cost-effective method for screening all the pregnant women in every trimester of pregnancy. According to DIPSI, one sample in non-fasting state is sufficient for diagnosing GDM. Women living in rural areas where minimal health care facilities are available this simple approach can reduce the mortality rate due to GDM.

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