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Original Research Article

Prevalence of gestational diabetes mellitus using IADPSG and DIPSI criteria: a cross-sectional study

Trupti C. Ruge*, Nisha Kanchana

Department of Obstetrics and Gynaecology, Navodaya Medical College, Raichur, Karnataka, India

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***Correspondence:**

Dr. Trupti C. Ruge,

E-mail: truptiruge87@gmail.com

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ABSTRACT

Background: Considering the magnitude of adverse pregnancy outcomes related to gestational diabetes, the present study was undertaken to find out the prevalence of gestational diabetes mellitus using the international association of diabetes in pregnancy study groups criteria (IADPSG) and diabetes in pregnancy study group India (DIPSI) criteria to ascertain whether the present practice of diagnosing GDM by the guidelines recommended by DIPSI 21 based on WHO criterion of 2-h PG ≥ 140 mg/dL can still be followed in this study settings or adopt IADPSG recommendation.

Methods: This study was done at Antenatal Clinic, department of obstetrics and gynecology, KLES Dr Prabhakar Kore Hospital, Belgaum from January 2013 to December 2013. A total of 225 pregnant women between 24 to 28 weeks gestations were studied. Diagnosis and the prevalence of GDM were assessed by applying both DIPSI and IADPSG criteria.

Results: Most of the women (58.11%) were between 22 to 25 years and the mean age was 23.78 ± 3.38 years. Based on the IADPSG criteria, the prevalence of GDM was 19.11% and by applying DIPSI criteria, prevalence of GDM was 16.89%. The difference in diagnostic capability between IADPSG and DIPSI was found to be 2.8% and the kappa statistics showed good strength of agreement between the two tests ($p > 0.302$; Kappa=0.774).

Conclusions: It was concluded that, the diagnosis GDM based on DIPSI is as effective as IADPSG criteria. Further, in resource poor countries like India, DIPSI procedure would be used with an advantage of being less costly and without compromising the clinical equipoise.

Keywords: Diabetes in pregnancy study group of India criteria, Gestational diabetes mellitus, International association of diabetes in pregnancy study groups criteria

INTRODUCTION

In most Asian countries, the economic prosperity is increasing. This has implications for the way people live, what they eat and patterns of disease they experience. China, India and several South East Asian nations are experiencing a rise in obesity and diet related non-communicable diseases. Type 2 diabetes mellitus has been documented to be increasing in Asia, although the increase seems to be greater in South Asia compared to East and South East Asia.^{1,2} It was estimated that globally in 2011, 366 million people were living with diabetes.

This is predicted to rise to 552 million people by 2030 with half of these living in Asia.³ Gestational diabetes mellitus (GDM) is defined as glucose intolerance first discovered in pregnancy. It is carbohydrate intolerance with onset or recognition during pregnancy.⁴

Depending on the diagnostic criteria used and the population screened, the prevalence of GDM ranges from 1.1 to 25.5% of pregnancies in the United States.⁵⁻⁹ In 2009 the centers for disease control and prevention reported a prevalence of 4.8% of diabetes in pregnancy. An estimated 0.5% of these cases likely represented

women with pregestational diabetes. Data from the international hyperglycemia and adverse pregnancy outcome (HAPO) study indicate that 6.7% of the women met a fasting plasma glucose threshold of 95 mg/dL (5.3 mmol/L), which is in keeping with the Carpenter and Coustan (CC) criteria that are in common practice in North America.^{7,9} In contrast, 17.8% of women were diagnosed with GDM using the international association of diabetes in pregnancy study groups (IADPSG) criteria in which lower glucose thresholds are proposed to diagnose GDM.^{5,10} The prevalence of GDM in India varies from 3.8 to 21% in different parts of the country, depending on geographical locations and diagnostic methods used.¹¹⁻¹⁴

Insulin is detectable in fetal pancreas as early as nine weeks after conception.¹⁵ An increase in beta cell mass and insulin secretion in the fetus occurs by the 16th week of gestation, in response to maternal hyperglycemia.¹⁶ The priming of the fetal beta cells may account for the persistence of fetal hyperinsulinemia throughout pregnancy and risk of accelerated fetal growth, even when the mother enjoys good metabolic control in later pregnancy.^{17,18} This necessitates performing the test procedures to diagnose GDM in the first trimester itself. Further, early detection and care results in a better fetal outcome.¹⁹

Studies conducted in different populations and with different methodologies, consistently reported an increase in GDM in all race/ethnicity groups, suggesting that there is an increase in GDM prevalence. A true increase in the prevalence of GDM aside from its adverse consequences for the infant in the new-born period might reflect or contribute to the ongoing pattern of increasing diabetes and obesity.

This implies that Universal screening and care of women with GDM is of paramount public health priority in high risk population for GDM and diabetes like Asian Indians, rather than risk factor screening. In this aspect, except the existing diagnostic criterion of World Health Organization (WHO) 2-h plasma glucose (PG) ≥ 140 mg/dL with 75g oral glucose load, other diagnostic criteria are country specific or recommended by various associations.²⁰

Currently diabetes in pregnancy study group of India (DIPSI) criteria is being used commonly in the community as it is difficult to get the patients in fasting state but since in a tertiary care hospital where patients come for regular antenatal follow up it is possible for them to report back during 24 to 28 weeks in a fasting state therefore this criteria can also be adopted to find the prevalence of GDM.²¹

Recently, based on the hyperglycemia and adverse pregnancy outcome (HAPO) study, the international association of diabetes and pregnancy study groups (IADPSG) consensus panel recommended that GDM can

be diagnosed, if any one value of fasting plasma glucose (FPG), 1-h and 2-h plasma glucose (PG) concentrations meet or exceed 92 mg/dL, 180 mg/dL and 153 mg/dL respectively, with 75g oral glucose tolerance test (OGTT).^{7,10} India one of the most populous countries in the world was not a part of the HAPO study.

The IADPSG recommends that the diagnosis of GDM be made when any of the following 75 grams of oral glucose, fasting, 1 hour, 2-hour oral glucose tolerance test (OGTT) thresholds are met or exceeded; fasting 92 mg/dL, 1 hour 180 mg/dL, or 2 hours 153 mg/dL.^{10,22}

Considering the magnitude of adverse pregnancy outcomes related to gestational diabetes the present study was undertaken to find out the prevalence of gestational diabetes mellitus using the IADPSG and DIPSI criteria to ascertain whether the present practice of diagnosing GDM by the guidelines recommended by DIPSI based on WHO criterion of 2-h PG ≥ 140 mg/dL can still be followed in this settings or adopt IADPSG recommendation.^{10,21,22}

METHODS

This cross-sectional study was conducted in the department of obstetrics and gynecology, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013. A total of 225 pregnant women between 24 to 28 weeks of gestation registered at antenatal clinic were studied. Known diabetic women and not consenting to participate in the study were excluded from the study. Prior to the commencement, ethical clearance was obtained from the Institutional Ethical committee, Jawaharlal Nehru Medical College, Belgaum, India.

The eligible women were explained about the nature of the study and a written informed consent was obtained. After the enrollment demographic data, obstetric history and current pregnancy details were obtained. Further these women were subjected to clinical examination.

Under aseptic precautions, 2 mL of venous blood sample was drawn in the fasting state. Further these women were given 75g oral glucose and their one hour and two hours venous blood samples were drawn. The plasma glucose was estimated in the hospital laboratory by glucose oxidase peroxidase (GOD-POD) method. Diagnosis and the prevalence of GDM were assessed by applying both DIPSI and IADPSG criteria.^{10,22}

Based on IADPSG criteria GDM was diagnosed if one or more values equals or exceeds thresholds of fasting plasma glucose of 5.1 mmol/L (92 mg/dL), one hour plasma glucose level of 10.0 mmol/dL (180 mg/dL) and two hour plasma glucose level of 8.5 mmol/L (153 mg/dL).^{10,22} Using DIPSI criteria GDM was diagnosed if after 75 grams oral glucose two hour plasma glucose value exceeds above 140 mg/dL.

Statistical analysis

The categorical data was expressed as rates, ratios and proportions and continuous data was expressed as mean ± standard deviation (SD). Difference in diagnostic capability between IADPSG and DIPSI was expressed in terms of percentage and Kappa statistics was used to evaluate the agreement. A probability value ('p' value) of less than or equal to 0.05 was considered as statistically significant.

RESULTS

The gestational age was 26 weeks in 26.67% of the women and mean gestational age was 26.25±2.70 weeks. Majority of the women (74.22%) had body mass index between 19.8 to 25.99 kg/m² and mean body mass index was 22.83±3.75 kg/m².

Table 1: Abnormal 75 g GTT at different intervals according to IADPSG criteria.

GDM (mg/dL)	Distribution (n=225)	
	Frequency	Percent
Fasting (≥92)	21	9.33%
One hour (≥180)	20	8.99%
Two hours (≥153)	17	7.56%

Table 2: Mean plasma glucose levels at different intervals.

Interval	Mean values (n=225) (mg/dL)	
	Mean	SD
Fasting	80.35	17.37
One hour	122.9	31.96
Two hours	107.76	29.51

The fasting, one hour and two hours plasma glucose levels were ≥ 92, ≥180 and ≥153 mg/dL in 9.33%, 8.99% and 7.56% of the women respectively (Table 1).

At same intervals the mean fasting plasma glucose levels were 80.35±17.37, 122.90±31.96 and 107.76±29.51 mg/dL respectively (Table 2). At different intervals, majority of abnormal cases were observed at fasting (5.78%) followed by 1 hour (4.89) and 2 hours (2.67%) (Table 3).

Table 3: Abnormal 75 g GTT at different intervals.

Intervals	Distribution (n=225)	
	Frequency	Percent
Fasting	13	5.78%
1 hour	11	4.89%
2 hours	6	2.67%
Fasting + 1 hour	2	0.89%
Fasting + 2 hours	4	1.78%
1 hour + 2 hour	5	2.22%
Fasting + 1 hour + 2 hours	2	0.89%
Normal	182	80.89%
Total	225	100.00%

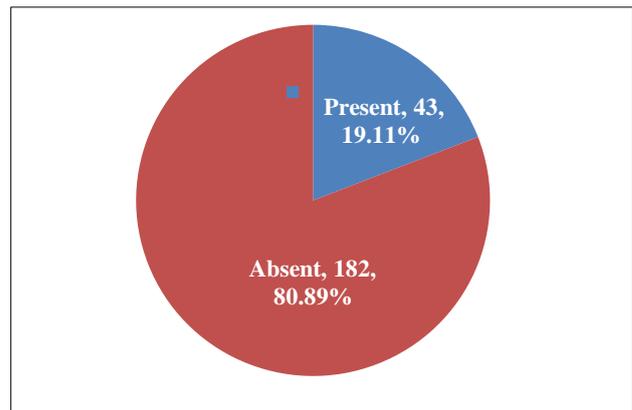


Figure 1: Prevalence of GDM based on IADPSG criteria.

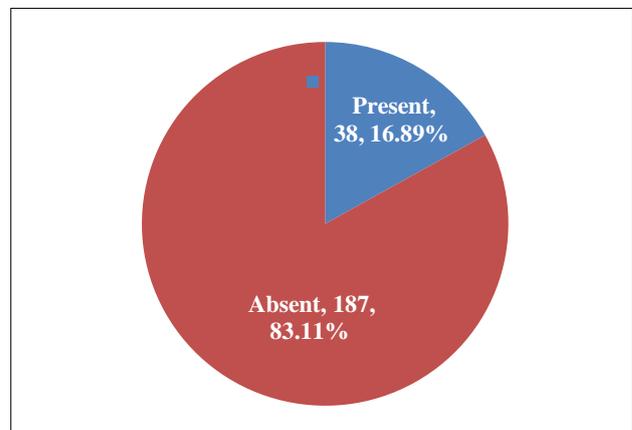


Figure 2: Prevalence of GDM based on DIPSI.

Table 4: Difference in diagnostic capability between IADPSG and DIPSI.

GDM based on DIPSI	GDM based on IADPSG				Total (n=120)	
	Present		Absent		No.	%
	No.	%	No.	%		
Present	33	86.84%	5	13.16%	38	16.89%
Absent	10	5.35%	177	94.65%	187	83.11%
Total	43	19.11%	182	80.89%	225	100.00%

Based on the IADPSG criteria, the prevalence of GDM was 19.11% (Figure 1) and by applying DIPSI criteria that is ≥ 140 mg/dL plasma glucose levels at two hours, prevalence of GDM was 16.89% (Figure 2). The difference in diagnostic capability between IADPSG and DIPSI was found to be 2.8% and the kappa statistics showed good strength of agreement between the two tests (Kappa=0.774, $p > 0.302$) (Table 4).

Hence it may be concluded that, the diagnosis GDM based on DIPSI is as effective as IADPSG criteria.

DISCUSSION

In the present study the prevalence of GDM was 19.11% based on IADPSG criteria and 16.89% according to DIPSI criteria. There is wide variation in the prevalence of GDM in India.²³ Earlier studies reported prevalence of 2% which rose to 7.62%.^{24,25} During 2002-2003, a random survey performed in various cities in India revealed prevalence of GDM as 16.2% in Chennai, 15% in Thiruvananthapuram, 21% in Alwaye, 12% in Bangalore, 18.8% in Erode and 17.5% in Ludhiana.²⁶ An overall GDM prevalence of 16.55 per cent was observed. Another study done in Tamil Nadu during 2005-2007, GDM was detected in 17.8%, 13.8% and 9.9% of the women in urban, semi-urban and rural areas, respectively.¹² The findings of the present study were consistent with the studies done in south India during the last decade.¹² However the wide variation in the prevalence rates of GDM may be attributed to the use of different criteria for diagnosis, variation in geographical region and life style with lack of physical activity.

In the present study, fasting, one hour and two hours plasma glucose levels were ≥ 92 , ≥ 180 and ≥ 153 mg/dL in 9.33%, 8.99% and 7.56% of the women respectively and at same intervals the mean fasting plasma glucose levels 80.35 ± 17.37 , 122.90 ± 31.96 mg/dL and 107.76 ± 29.51 mg/dL respectively. Based on the IADPSG criteria,^{10,22} the prevalence of GDM 19.11% and by applying DIPSI criteria that is ≥ 140 mg/dL plasma glucose levels at two hours, prevalence of GDM was 16.89%.²¹ The difference in diagnostic capability between IADPSG and DIPSI was found to be 2.8%.^{10,21,22} However the concordance observed was statistically not significant and the kappa statistics showed good strength of agreement between the two tests ($p > 0.302$; $p = 0.302$; Kappa=0.774; SE of kappa=0.056; 95% CI: From 0.665 to 0.883). These findings suggest that, to diagnose GDM, DIPSI procedure based on WHO criterion of 2- h PG ≥ 140 mg/dL is as effective as IADPSG criteria.^{10,21,22} Recently a similar study done in Chennai also found prevalence of GDM, as 13.4% and 14.6% using DIPSI and IADPSG criteria respectively.^{10,21,22} The difference in the diagnostic capability between IADPSG and DIPSI was 1.2% ($p > 0.02$).^{10,21,22}

The IADPSG recommendation requires estimation of plasma glucose in three blood samples after

administering 75g oral glucose load whereas, DIPSI criterion requires one blood sample drawn at 2-h for estimating the plasma glucose yielding to higher costs.^{10,22} Further DISPI requires little preparation, without requiring the prior interposition of the screening test and hence it could be applied at the community levels.²¹ Thus, DIPSI procedure would still serve the purpose of implementing public health program to diagnose GDM in the community.²¹

Surprisingly similar results were found on the comparison of IADPSG and the WHO criteria to diagnose GDM.^{10,22,27} A maiden study compared the IADPSG and the WHO criteria to diagnose GDM in Chennai, India.^{10,22,27} The study reviewed the retrospective data of 1351 pregnant women who underwent screening for GDM at four selected diabetes centers at Chennai (three private and one government). All women underwent an oral glucose tolerance test using 75 g glucose load and fasting, 1-hour, and 2-hour samples were collected. The IADPSG and WHO criteria were compared for diagnosis of GDM.^{10,22,27} A total of 839 women had GDM by either the IADPSG^{10,22} or the WHO criteria, of whom the IADPSG criteria identified 699 and the WHO criteria also identified 699 women as having GDM.^{10,22,27} However, only 599/839 women (66.6%) were identified by both criteria. Thus, 140/839 women (16.7%) were missed by both the IADPSG and the WHO criteria.^{10,22,27} 687/699 (98.2%) of the women with GDM were identified by the WHO criteria.²⁷ In contrast, each value of IADPSG criteria^{10,22} i.e., fasting, 1 hour, and 2 hour identified only 12.5%, 14%, and 22%, respectively. A single WHO cut-point of 2 hours > 140 mg/dl appears to be suitable for large-scale screening for GDM in India and other developing countries.

The WHO first proposed criteria for GDM using a 75 g OGTT in the 1980s.^{28,29} In its technical report published in 1994, it defined GDM as DM first recognized during pregnancy, and gestational impaired glucose tolerance (GIGT) as IGT first recognized during pregnancy.³⁰ In 1998, WHO recommended new criteria.³¹ With regard to GDM, pregnant women who met the WHO criteria²⁷ for DM or IGT were classified as having GDM and, therefore, the term GIGT disappeared. Some studies have been published taking FPG > 126 mg/dl as the criteria for GDM.³² However, the more recent studies have altogether ignored the FPG criteria and have used only the 2-hour > 140 mg/dl criteria of the WHO.³³ When the ADA lowered the FPG to 100 mg/dl from the previous 110 mg/dl for diagnosis of impaired fasting glucose in non-pregnant adults, the FPG level of 126 mg/dl in pregnancy started looking too high and most people just chose to ignore the FPG level for the diagnosis of GDM. However, till date, there is no official recommendation from WHO to drop FPG criteria and to follow only the 2-h value of 140 mg/dl.³⁴

It appears an anomaly that in the WHO criteria, the fasting cut-off had been set at 126 mg/dl which is

diagnostic of diabetes in non-pregnant adults, whereas the 2-h cut-off was set at 140 mg/dl, which is the diagnostic cut-point for IGT in non-pregnant adults.²⁷ Probably because of this inherent contradiction in the diagnostic criteria, the fasting values in the WHO criteria are not particularly useful to diagnose GDM and this might explain why the WHO 2-hour value alone picked up over 98% of all cases diagnosed by both fasting and 2-hour WHO criteria in this study.²⁷ Another point to be noted is that if a pregnant woman has a FPG \geq 126 mg/dl, it is considered overt diabetes complicating pregnancy, and not as GDM, by the IADPSG criteria.^{10,22}

Another issue of concern is whether too many women would get diagnosed as GDM because of the low FPG cut-off in the IADPSG criteria.^{10,22} Indeed, of the 88 women who were diagnosed as GDM by virtue of their FPG abnormality alone using IADPSG criteria, only 30 (34%) were classified as GDM by the WHO criteria.^{10,22,27} A similar comparison with those with GDM according to the IADPSG 1-hour cut-off value showed that only 47/98 (48%) had GDM by WHO criteria.²⁷ It is thus possible that by reducing the FPG cut-point to 92 mg/dl, we could be over-diagnosing GDM in normal pregnant women. This could lead to overloading of the health systems in many countries.³⁵

Earlier reports have shown that the sensitivity of the 2-hour value in the glucose tolerance test (GTT) is much higher than the fasting plasma glucose among non-pregnant Indian adults.³⁴ Thus, it is reasonable to assume that since the IADPSG has raised the 2-hour value in the IADPSG to 153 mg/dl, many cases of GDM could be missed.³⁵

The finding of the present study were in agreement with a study done in Chennai despite the methodological differences that is, difference in study design, criteria used to diagnose GDM and sample size.³⁵

Overall, the present study showed that, DIPSI procedure based on WHO criterion of 2-hour PG \geq 140 mg/dL would be cost-effective without compromising the clinical equipoise.²⁷ However the limitations of the study were the study did not consider the diagnostic capability in different confounding variable such as maternal age, parity and obesity as it was beyond the scope of this study. However, association between parity and diabetes is strongly linked to obesity and age. Women with higher parity frequently are older and more obese. Obesity is an intermediate outcome in the causal pathway between parity and gestational diabetes mellitus, probably a mediating factor. However, age is a potential confounder in the association between parity and gestational diabetes mellitus.³⁶ Hence further studies with large sample size considering the age, parity and obesity would enlighten the role of DIPSI in the diagnosis of GDM.

One of the limitations of the study is that with this present data, authors cannot conclude whether IADPSG

or DIPSI criteria is better for Indian pregnant women as authors do not have data on the maternal and fetal outcomes which was beyond the scope of this study.^{10,20,21} In the absence of the outcome data, which however, was beyond the purview of the study, it was not possible to comment on the suitability of diagnosing GDM by either of the two criteria in this population. Nonetheless, this study compared the ease of use of two criteria in the population studied. Future studies should compare the outcomes of the GDM cases diagnosed by IADPSG and DIPSI criteria as this would provide the final answer as to which criteria is more suitable for Indians.^{10,21,22}

CONCLUSION

From the present study, it was concluded that, the diagnosis GDM based on DIPSI is as effective as IADPSG criteria. Further, in resource poor countries like India, DIPSI procedure would be used with an advantage of being less costly and without compromising the clinical equipoise.

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