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ORIGINAL ARTICLE

Diagnostic Accuracy of Diabetes in Pregnancy Study Group of India with Carpenter–Coustan and National Diabetes Data Group Criteria for Diagnosis of Gestational Diabetes Mellitus and Correlation with Fetomaternal Outcome

Pikee Saxena[1] · Tanya Shubham[1] · Manju Puri[1] · Anju Jain[2]

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Abstract

Background No previous study compared ACOG and DIPSI criteria for diagnosing gestational diabetes (GDM). This study compared diagnostic accuracy of Diabetes in pregnancy study group of India (DIPSI) with Carpenter–Coustan (CC) and National Diabetes Data Group (NDDG) criteria for diagnosis of GDM and correlation with fetomaternal outcome.

Methods A total of 1029 pregnant women underwent 2 h 75 g OGTT in non-fasting state. After 3–7 days, women were called in fasting state and subjected to 100 g OGTT and fasting, 1, 2, 3 h samples were taken. GDM was diagnosed using DIPSI, CC and NDDG criteria. All women were followed till delivery, and fetomaternal outcome was noted.

Results 10.4% (107) women were diagnosed as GDM by DIPSI, 6.4% (66) by CC and 3.1% (32) by NDDG criteria. Sensitivity of DIPSI with CC was 98.48%, specificity was 95.64%, and diagnostic accuracy was 95.82%. Sensitivity of DIPSI with NDDG was 99.89%, specificity was 92.38%, and diagnostic accuracy was 95.52%. Sensitivity of NDDG with CC was 48.48%, specificity was 100%, and diagnostic accuracy was 96.7%. Women with GDM by all three criteria were seen to have a significantly higher proportion of LSCS, higher birth weight and macrosomia compared to normoglycemic women (p value < 0.001).

Conclusion Diagnostic accuracy, sensitivity and specificity of DIPSI are comparable to CC and NDDG criteria; therefore, DIPSI can be recommended for diagnosing GDM with added advantage of low cost, simplicity and convenience. Women diagnosed as GDM by DIPSI, CC and NDDG had significantly higher rate of cesarean delivery, higher birth weight and macrosomia as compared to women with normoglycemia.

Keywords DIPSI · CC · NDDG for GDM

Introduction

Gestational diabetes mellitus (GDM) is one of the leading public health problems all over the world which is associated with not only adverse fetomaternal outcomes but also long-term morbidities for the mother and the offspring. Therefore, early diagnosis of GDM is important to attain normoglycemia and avoid these complications.

A number of criteria have been proposed for the diagnosis of GDM, but there is no universal consensus regarding the most accurate and feasible test which is acceptable to all. The American College of Obstetrics and Gynecology (ACOG) and American Diabetes Association (ADA) both recommend ACOG Criteria for diagnosis of GDM. ACOG has recommended Carpenter and Coustan (CC) and National

Dr. Pikee Saxena is M.D. Obstetrics and Gynecology, FICOG, MNAMS, FMAS, Postgraduate Certificate Course in Hospital Management, Postgraduate Diploma in Clinical Research and a Professor at the prestigious Lady Hardinge Medical College & SSK Hospital, New Delhi, India; Tanya Shubham is a M.D., Resident , Department of Obstetrics and Gynecology, Lady Hardinge Medical College & SSKH, New Delhi, India; Manju Puri is a M.D., Director Professor, Department of Obstetrics and Gynecology, Lady Hardinge Medical College & SSKH, New Delhi, India; Anju Jain is a M.D., Director Professor, Department of Biochemistry, Lady Hardinge Medical College & SSKH, New Delhi, India.

✉ Pikee Saxena
pikeesaxena@hotmail.com

Extended author information available on the last page of the article

Diabetes Data Group (NDDG) criteria which is being followed in many parts of the world although it requires 2 visits and 5 times plasma glucose measurement [1]. This test is a technical, economic and practical challenge for the developing nations where the antenatal coverage is suboptimal and is also a strain for the pregnant women who have to travel for long distances in a fasting state and undergo painful blood sampling repeatedly. In addition, there is a high chance of the woman not returning for a second visit which leads to missing the diagnosis of diabetes in these women.

Indians have higher risk of developing diabetes, and therefore, universal screening for GDM is recommended [2]. Ministry of Health and Family Welfare, India, has recommended the use of DIPSI in India because it simple, economical and convenient. FIGO 2015 also endorses the test for medium to low resource settings [3], but there is no uniformity regarding the diagnostic test used for diagnosis of GDM in different parts of the country. There is confusion about the diagnostic accuracy of DIPSI even in the mind of health providers due to controversial reports. No previous study has compared the diagnostic accuracy of DIPSI with ACOG criteria of CC and NDDG or evaluated their relation with maternal and fetal wellbeing. Therefore, this study was planned to evaluate the diagnostic accuracy of DIPSI with CC and NDDG criteria for diagnosis of GDM and correlate with fetomaternal outcome.

Materials and Methods

This study was conducted between November 2017 and March 2019 on pregnant women irrespective of gestational age attending antenatal clinic and admitted in antenatal ward of Department of Obstetrics and Gynecology in association with Department of Biochemistry in a tertiary care teaching hospital. Already diagnosed cases of diabetes mellitus were excluded.

The study was initiated after obtaining permission from the Ethics Committee of Human Research (ECHR), and all participants were recruited after taking a written informed consent.

One thousand sixty-one women were approached of which 8 were found to be overt diabetic and 24 women refused to participate in the study. One thousand twenty-nine women were recruited in this study and were administered 75 g oral glucose load irrespective of their fasting state during their antenatal visit. After 2 h, a venous sample for plasma glucose level was withdrawn to assess for GDM according to DIPSI criteria. All women were called for a second visit between 3 and 7 days after 8–10 h of fasting, and venous sample was taken to take a sample for fasting plasma glucose. This was followed by administration of 100 g glucose load, and thereafter, three venous samples were drawn at hourly intervals (1, 2, 3 h) to determine plasma glucose levels by CC and NDDG criteria. Diagnosis of gestational diabetes mellitus was made if:

DIPSI Criteria [2] Plasma glucose level was ≥ 140 mg/dl after 75 g glucose load irrespective of fasting status.

CC Criteria [1] Fasting plasma glucose ≥ 95 mg/dl, 1 h ≥ 180 mg/dl, 2 h ≥ 155 mg/dl and 3 h ≥ 140 mg/dl after 100 g glucose load; GDM is diagnosed if ≥ 2 values are above threshold.

NDDG Criteria [1] Fasting blood sugar ≥ 105 mg/dl, 1 h ≥ 190 mg/dl, 2 h ≥ 165 mg/dl and 3 h ≥ 145 mg/dl after 100 g glucose load; GDM is diagnosed if ≥ 2 values are above threshold.

Sample size was computed as in a diagnostic test study with calibrated outcome. As this was a pilot study, sensitivity of the candidate test was assumed to be is 85% (with absolute precision of ± 10%) in comparison to gold standard. Further assuming prevalence of gestational diabetes mellitus to be 10% [4] and margin of error 7%, a sample size of 980 was computed. Assuming 5% loss to follow-up, total sample size was calculated to be 1029 women. Statistical analysis was performed using SPSS software for windows version 21.

Results

Age of pregnant women ranged between 18 and 44 years. BMI of women ranged between 17.1 and 31.7 kg/m^2. Mean BMI of GDM women was 23.13 ± 2.83 kg/m^2 by DIPSI, 23.41 ± 2.9 kg/m^2 by CC and 24 ± 2.93 kg/m^2 by NDDG criteria.

Women with positive family history of DM are at increased risk of developing GDM in pregnancy and type 2 DM later in life. Family history of DM was present in 4.67% of women diagnosed as GDM by DIPSI criteria, 7.58% by CC criteria and 9.38% by NDDG criteria. History of abortions in previous pregnancies was present in 28.04% of women diagnosed as GDM by DIPSI criteria, 30.3% by CC and 37.5% by NDDG criteria. History of stillbirth in previous pregnancies was present in 12.15% diagnosed as GDM by DIPSI criteria, 13.64% by CC criteria and 21.88% by NDDG criteria.

In the present study, 10.4% (107/1029) of the women were found to be having GDM by DIPSI criteria, 6.4% (66/1029) by CC and 3.1% (32/1029) by NDDG criteria (Fig. 1).

All the women included in the study were followed till delivery. Lower segment cesarean section was performed

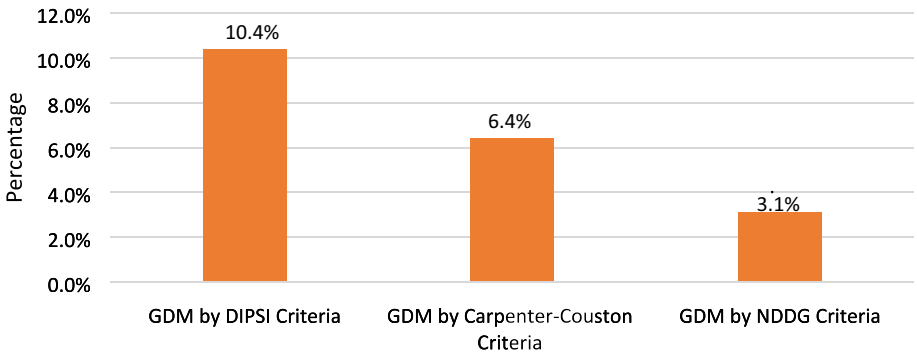

Fig. 1 Prevalence of GDM by DIPSI, CC and NDDG

Table 1 Mode of delivery of GDM and normoglycemic women diagnosed by DIPSI, CC and NDDG

Criteria	LSCS	*p* value
DIPSI		
GDM	25 (23.36%)	0.023
Normoglycemic	134 (14.53%)	
CC		
GDM	17 (25.76%)	0.022
Normoglycemic	142 (14.75%)	
NDDG		
GDM	11 (34.38%)	0.006
Normoglycemic	148 (14.84%)	

Table 2 Birth weight of neonates of GDM and normoglycemic women diagnosed by DIPSI, CC and NDDG

Criteria	Neonate of GDM mother		Normoglycemic neonate		Test of significance
	Mean (kg)	SD	Mean (kg)	SD	*p* value
DIPSI	2.95	0.46	2.42	0.35	< 0.001
CC	3.15	0.46	2.43	0.35	< 0.001
NDDG	3.41	0.43	2.45	0.36	< 0.001

in 23.36% of women diagnosed as GDM by DIPSI criteria, 25.76% by CC criteria and 34.38% by NDDG criteria (Table 1).

Mean birth weight of women diagnosed as GDM was 2.95 ± 0.46 kg by DIPSI, 3.15 ± 0.46 kg by CC and 3.14 ± 0.43 kg by NDDG (Table 2). Prevalence of macrosomia in GDM women diagnosed by DIPSI, CC and NDDG is depicted in Table 3.

Table 3 Prevalence of macrosomia in mothers of neonates diagnosed by DIPSI, CC and NDDG

Criteria	Macrosomia	*p* value
DIPSI		
GDM	18 (16.8%)	< 0.001
Normoglycemic	6 (0.7%)	
CC		
GDM	18 (27.3%)	< 0.001
Normoglycemic	6 (0.6%)	
NDDG		
GDM	16 (50%)	< 0.001
Normoglycemic	8 (0.8%)	

Discussion

The prevalence of GDM is seen to vary according to the diagnostic criteria used because of the varying degree of glucose intolerance detected by different criteria. Prevalence of GDM in the present study was 10.4% (107/1029) by DIPSI, 6.4% (66/1029) by CC and 3.1% (32/1029) by NDDG criteria. This implies that almost 40% women with GDM were being missed by CC and almost 70% of GDM women were being missed by NDDG when compared to DIPSI test.

The prevalence of GDM varied significantly when compared by the two ACOG recommended tests, and nearly 50% diagnosed by CC were missed by NDDG criteria.

Lu et al. reported that 6.16% women had GDM by CC criteria and 4.0% women had GDM by NDDG criteria [5]. Karcaalticaba et al. also found prevalence of GDM by NDDG to be 3.17% and 4.48% by CC [6]. In a previous study conducted by Saxena et al. to compare diagnostic accuracy of DIPSI and HbA1c with WHO OGTT as gold standard, prevalence of GDM was 6.37% by WHO criteria, 7.8% by DIPSI criteria and 5% by HbA1c [7].

It is known that Indians have a higher insulin resistance, and therefore, although their fasting plasma glucose values

are within normal limit, their 2-h post-glucose value is exaggerated [8]. This is evident in this study where fasting threshold picked up 68.2% women with GDM, whereas 2-h post-glucose value picked up 93.9% women with GDM. It was observed that maximum number of women had a deranged 2-h plasma glucose value by both CC and NDDG criteria and most of these women with deranged 2-h value also had higher fasting 1, 2 or 3-h value (Fig. 2). As DIPSI picks up hyperglycemia at 2-h post-glucose load, almost all of these women are identified by DIPSI.

A woman is said to have impaired glucose tolerance (IGT) if one value is above threshold according to CC or NDDG criteria. 3.9% had impaired glucose tolerance by CC criteria, and 2.4% had impaired glucose tolerance by NDDG criteria. Among women who had IGT by CC criteria, 25% (10) were diagnosed as GDM by DIPSI criteria and among women who had IGT by NDDG criteria, 76% (19) were diagnosed as GDM by DIPSI. Significantly higher proportion of women with IGT by both criteria were diagnosed as GDM by DIPSI criteria.

Sensitivity of DIPSI compared to CC was 98.48%, specificity was 95.64%, positive predictive value was 60.75%, negative predictive value was 99.89%, and diagnostic accuracy was 95.82%. Percentage of agreement between DIPSI and CC criteria was 95.82%.

Sensitivity of DIPSI compared to NDDG was 99.89%, specificity was 92.38%, positive predictive value was 28.97%, negative predictive criteria was 92.5%, and diagnostic accuracy was 95.52%. Percentage of agreement between DIPSI and NDDG standard was 96.88%.

On comparing the two ACOG tests, sensitivity of NDDG compared to CC was 48.48%, specificity was 100%, positive predictive value was 100%, negative predictive value was 96.59%, and diagnostic accuracy was 96.7%. Percentage of agreement between NDDG and CC criteria was 96.7%.

All women enrolled in this study were followed up till delivery. Women with GDM by all 3 criteria were seen to have a significantly larger proportion of women who underwent LSCS ($p < 0.001$; Table 1). There was a significant difference in birth weight between normoglycemic women and women with GDM by DIPSI, CC and NDDG criteria ($p < 0.001$; Table 2). Fetopelvic disproportion was found to be a major indication for LSCS in women with GDM by all 3 criteria (DIPSI 32%; CC 47%; NDDG 63.7%).

Although ACOG defines macrosomia as birth weight > 4.5 kg [9], in India macrosomia is defined as birth weight ≥ 3.45 kg [10]. Macrosomia was seen in significantly higher proportion in all cases of GDM as compared to normoglycemic women (Table 3). As can be seen from the table, no patient with macrosomia was missed by DIPSI criteria with respect to CC, but NDDG missed 2 women with mild hyperglycemia who presented with macrosomia.

In this study, it was noted that DIPSI was able to detect even mild degree of glucose intolerance, whereas CC criteria detected moderate degree of glucose intolerance and NDDG criteria detected the most severe form.

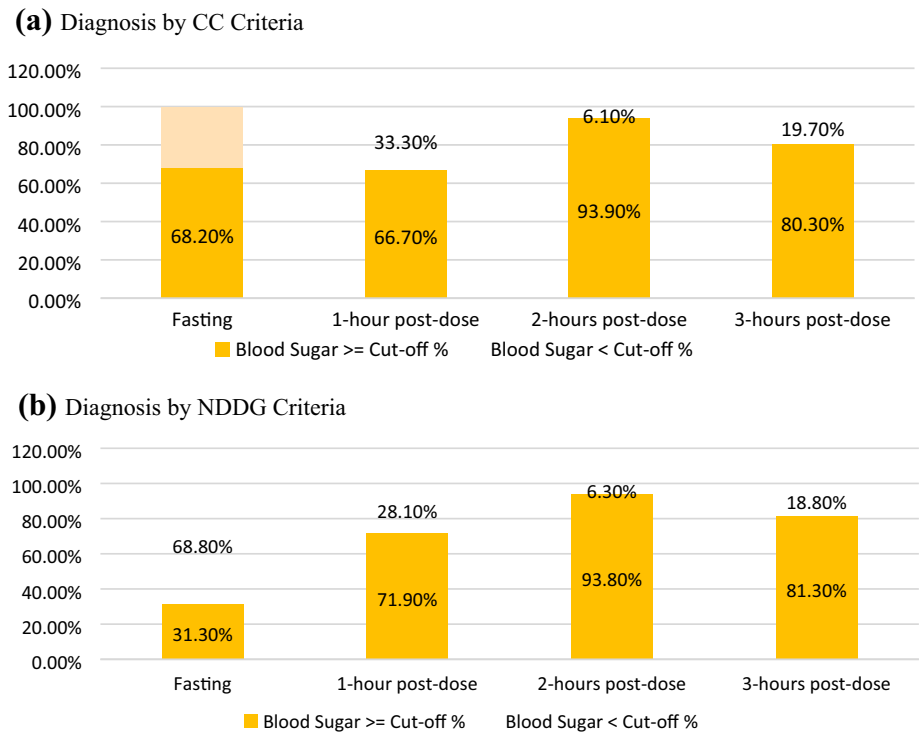

Fig. 2 Percentage of women with plasma glucose levels above threshold according to timing of the test by CC and NDDG

There have been no previous studies comparing the diagnostic accuracy of DIPSI with ACOG criteria. Although ACOG recommends both CC and NDDG criteria for diagnosis of GDM they have different threshold values and prevalence of GDM by both criteria varies considerably [1, 5]. It is important to note that DIPSI is not missing any women with hyperglycemia diagnosed by CC and NDDG. DIPSI is also able to detect a good proportion of women who had IGT by CC or NDDG criteria and thus identifies women with mild degree of hyperglycemia. HAPO study has proven that the relationship between maternal glucose levels and adverse fetal outcomes is not clearly demarcated and even mild degree of maternal hyperglycemia is associated with adverse fetomaternal outcomes [11]. Also, majority of the mild hyperglycemia picked up by DIPSI require only lifestyle modifications and not pharmacotherapy which is beneficial for them in the long run. Since the diagnostic accuracy, sensitivity and specificity of DIPSI with respect to both CC criteria and NDDG criteria are comparable, DIPSI can be used for diagnosis of GDM in resource restricted countries as it is simple, economic, convenient and is done in a single visit in a non-fasting state. Women diagnosed as GDM by DIPSI, CC and NDDG had significantly higher rate of cesarean delivery, higher birth weight and macrosomia as compared to women with normoglycemia.

Declarations

Conflict of interest The authors have no conflict of interest in the findings of this study.

Human and Animal Rights All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Ethical Standards This study was initiated after approval from the Ethics Committee of Human Research of the Institute.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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About the Author

Pikee Saxena is a M.D. Obstetrics and Gynecology, FICOG, MNAMS, FMAS, Postgraduate Certificate Course in Hospital Management, Postgraduate Diploma in Clinical Research and a Professor at the prestigious Lady Hardinge Medical College and SSK Hospital, New Delhi, India. She has more than 100 International & National publications, awarded 29 Gold medals for her research work in both National & International forum, in charge of IUI Lab and Infertility Clinic at LHMC, Nodal Officer of National Skills Lab, LHMC, Principal Investigator of several research projects including DST & ICMR, Editor of 3 books of Obstetrics and Gynecology, Editor of the Journal of Delhi Diabetic Forum, Senior Executive Editor IJMS, Co-Editor of the PAJOG, member of Infertility Committee, Safe Motherhood Committee of AOGD.

Authors and Affiliations

Pikee Saxena[1] · Tanya Shubham[1] · Manju Puri[1] · Anju Jain[2]

[1] Department of Obstetrics and Gynecology, Lady Hardinge Medical College and SSKH, J-36 Saket, New Delhi 110017, India

[2] Department of Biochemistry, Lady Hardinge Medical College and SSKH, New Delhi, India