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To study the comparison of the efficacy of DIPSI, IADPSG, and GCT criteria as a screening test for gestational diabetes mellitus in Indian patients

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Abstract

Gestational Diabetes Mellitus increases the risk of unfavourable maternal, perinatal, and foetal outcomes in females, necessitating early detection and treatment. The DIPSI, IADPSG, and GCT criteria for screening of Gestational Diabetes Mellitus in Indian patients were compared in this prospective cross-sectional study, which involved a total of 250 women with a gestational age of between 24-28 weeks. GDM screening and diagnostic procedures will be presented and contrasted, followed by an assessment of various glycemic thresholds. The comparison was made based on the specificity and sensitivity of various criteria, and it was discovered that a single-step 75-g OGTT utilizing the IADPSG criteria should be performed in the fasting state whenever possible. In resource-constrained settings, such as rural areas, a well-validated two-step approach uses a non-fasting 50 g GCT as the initial screening test, followed by a fasting OGTT for conclusive diagnosis in those who screen positive.

Keywords: Gestational diabetes mellitus, GDM, DIPSI, IADPSG, GCT, criteria, outcome

Introduction

Glucose intolerance with the onset or first recognition during pregnancy is defined as Gestational Diabetes Mellitus (GDM) [1]. Females with GDM are at an increased risk of adverse maternal and perinatal outcomes [2]. They and their children are also at increased risk of future diabetes, therefore there are two generations at risk [2]. The adverse maternal complications include preeclampsia, hypertension, urinary tract infection, polyhydramnios, increased rate of operative interventions, and future DM. In the fetus and neonates, it is associated with macrosomia, congenital anomalies, metabolic abnormalities, RDS, etc. and subsequent development of obesity [3]. Therefore, early diagnosis and prompt treatment are mandatory. GDM affects 7% of all pregnancies worldwide and in India, it ranges from 6 to 9% in rural and 12 to 21% in urban areas [4]. It is diagnosed in 16.3% at ≤ 16 weeks of gestation, 22.4% between 17-23 weeks of gestation, and 61.3% after 23 weeks of gestation [5]. The high prevalence of DM and genetic predisposition to it among Asians, particularly in Indian women, predisposes females to develop GDM. So, there is a need for cost-effective universal screening and diagnostic methods. Unfortunately, there is no international consensus on the screening and diagnostic criteria for GDM.

A screening test should have high sensitivity so that we can identify the maximum number of patients with GDM. Several criteria are available for screening of GDM with each having its own merits and demerits (Table 1). The Diabetes in Pregnancy Study Group of India (DIPSI) guidelines suggest that a non-fasting OGTT using a 2-h VPG value of 140 mg/dl (7.8 mmol/l) can be used as a single-step, definitive, screening and diagnostic test for GDM [8-10]. These guidelines were based on a single-centre study [15] from southern India which reported a 100% sensitivity and 100% specificity for this cut point compared to the WHO 1999 criteria, which also uses the same cut point of 140 mg/dl [7.8 mmol/l] but with the OGTT done in the fasting state.

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Table 1: Various criteria proposed for diagnosing GDM based on fasting OGTT.

Criteria	Year proposed	Approach	Glucose Load (g)	Glucose Threshold mg/dl (mmo1/1)			
				Fasting	1h	2h	3h
O'Sullivan & Mahan	1964	2 steps	100	90 (5.0)	165(9.2)	145(8.1)	125(6.9)
National Diabetes Data Group (NDDG)	1979	2 steps	100	105 (5.8)	190 (10.6)	165 (9.2)	145 (8.1)
Carpenter & Clouston	1982	2 steps	100	95 (5.3)	180 (10.0)	155 (8.6)	140 (7.8)
World Health Organization (WHO)	1999	1 step	75	126' (7.0)	—	140 (7.8)	—
American Diabetes Association (ADA)	2004	2 steps	100	95 (5.3)	180 (10.0)	155 (8.6)	140 (7.8)
Latin American Diabetes Association (ALAD) ^b	2008	2 steps	75	100 (5.5)	—	140 (7.8)	—
International Association of Diabetes and Pregnancy Study Groups (IADPSG)	2010	1 step	75	92 (5.1)	180 (10.0)	153 (8.5)	—
World Health Organization 2013 criteria (revised, same as IADPSG)	2013	1 step	75	92 (5.1)	180 (10.0)	153 (8.5)	—
National Institute for Health and Care Excellence (NICE)	2015	1 step	75	101 (5.6)	—	140 (7.8)	—

Adopted from (Vandorsten *et al.*, 2011) ^[12], Values in parenthesis are in mmol/l, later this fasting value was dropped, bCriteria for the diagnosis of gestational diabetes in selected countries of the Americas. Final report of the Pan American Conference on Diabetes and Pregnancy ^[14].

In a resource-limited setting like India, where nearly 70% of the population lives in rural settings ^[16], DIPSI felt that there was a

need to develop a simple and economical method of diagnosing GDM. The DIPSI criteria, because of its sheer simplicity, has been widely accepted and used in many parts of India and Sri Lanka ^[17] and other South Asian countries. WHO (1999) recommends a fasting OGTT after 75g of glucose with cut-off plasma glucose of ≥ 140 mg/dl after 2 hours.

Table 2: IADPSG criteria for diagnosis of GDM and overt diabetes in pregnancy ^[11].

First Prenatal Visit	Measure FPG, HbA 1 c or RPG	<ul style="list-style-type: none"> Overt diabetes if, FPO> 126 mg/dl (7.0 mmo1/1) Or random plasma glucose > 200 mg/dl(11.1 mmo1/1) Or HbA1 c> 6.5 VoGDM if, FPG > 92 mg/dl (5.1 mmo1/1) but <126 mg/dl (7.0 nuno1/1)
If the test is normal in the first prena al visit, test for GDM dining 24-28 weeks		
24-28 weeks of gestation	75 g OGTT	<ul style="list-style-type: none"> Pre-existing diabetes if FPG> 126 mg/dl (7.0 nuno1/1)GDM if, FPG>92 mg/dl (5.1 mmo1/1) 1 11> 180 mg/dl (10.0 nuno1/1) 211> 153 mg/di (8.5 nuno1/1)

The recommendations by ADA/IADPSG for screening women at risk of diabetes are as follows: for first and subsequent trimesters at 24-28 weeks, a criterion of diagnosis of GDM is made by 75 g OGTT and fasting ≥ 92 mg/dl, 1 hour ≥ 180 mg/dl, 2 hours ≥ 153 mg/dl by universal glucose tolerance testing. The ACOG still prefers a two-step procedure, GCT with 50g glucose non-fasting if the value is >140 mg/dl after one hour, followed by 3-hour OGTT for confirmation of diagnosis. The IADPSG criteria (Table 2) is the only outcome-based criteria derived from the Hyperglycaemia and Adverse Pregnancy Outcomes (HAPO) study, it has the ability to diagnose and treat GDM earlier, thereby reducing the fetal and maternal complications associated with GDM. Keeping in the mind the diversity and variability of the Indian population, judging international criteria may not be conclusive, thus further comparative studies are required on different diagnostic criteria concerning adverse pregnancy outcomes. This study is being conducted to compare the DIPSI, IADPSG, and GCT criteria for screening of GDM in Indian patients.

Material and Method

This was a prospective cross-sectional study done at the department of obstetrics and gynaecology at Base Hospital Delhi Cantt, a tertiary care centre in North India. A total of 250 consecutive pregnant women attending an outpatient department with a gestational age of between 24-28 weeks were enrolled in the study. Institutional Ethics committee approval was obtained before commencing with the study and written informed consent was taken from all the participants of the study. Patients who are known case of diabetes mellitus, who did not give written

consent and who vomited after ingestion of glucose. Pregnant females enrolled in the study at their first visit were subjected to non-fasting GCT using a 50 g oral glucose load, which was administered irrespective of the timing of the last meal. A venous blood sample was drawn one hour after the glucose administration. All enrolled women were again asked to come after 3 days for non-fasting for DIPSI using a 75g oral glucose load which was administered irrespective of the timing of the last meal. A venous blood sample was drawn 2 hours after the glucose administration. The patients after 3 days were called again with overnight fasting for at least 8 hours duration for a 75-g OGTT. This time, venous samples were drawn at fasting, 1 and 2 h after the glucose load. Blood samples were collected in sodium fluoride/Na₂ EDTA vacutainer tubes to prevent glycolysis. Plasma glucose was measured using an autoanalyzer. Patients were diagnosed as a case of GDM if they fulfilled predefined criteria. For IADPSG criteria- any one of the following, i.e. fasting ≥ 92 mg/dl (5.1 mmol/l), 1 h ≥ 180 mg/dl (10 mmol/l) and 2 h ≥ 153 mg/dl (8.5 mmol/l) ^[7]. For DIPSI criteria: 2-h VPG ≥ 140 mg/dl (7.8 mmol/l) after non-fasting 75gm OGTT. GCT criteria: one-hour VPG ≥ 140 mg/dl after non-fasting 50gm GCT.

Patients were divided into subgroups like having all criteria positive, two criteria positive, and only one criterion positive. Statistical analysis will be done to assess the efficacy of the above-mentioned criteria and establish a correlation between them.

Categorical variables are presented in number and percentage (%) and continuous variables as mean \pm SD. Normality of data was tested by Kolmogorov-Smirnov test. Quantitative variables

were compared using the student t-test. Qualitative variables were compared using the Chi-Square test /Fisher's exact test. The student's paired t-test was applied to test the difference between values obtained by different methods. Pearson correlation was used to see the relation between two variables. Statistical software SPSS version 16.0 was used to analyse the data. Alpha value (p-value) less than 0.05 was considered as significant at a 95% confidence level.

Results

A total of 250 pregnant women in 24 to 28 weeks of pregnancy were enrolled in the study. These women underwent the initial non- fasting GCT with 50-gram glucose. Five (2%) women

vomited after consuming the glucose, and they were excluded from further analysis. The remaining 245 women were requested to come back 3 days later, for the non-fasting OGTT (DIPSI), of whom 234 (95.5%) came back for the test. Of these 234 women, six (2.6%) vomited after consuming the glucose and they were excluded. The remaining 228 were called again for a third visit after 3days for fasting OGTT. Out of these 228 women, 226 (99.12%) came back for the test. Of these 226 women, eight (3.5%) had vomiting after the test and were excluded. The remaining 218 women were included in the study for further data analysis (Figure 1). There was no significant difference in the number of women who vomited during the fasting and non-fasting OGTT (p=0.18).

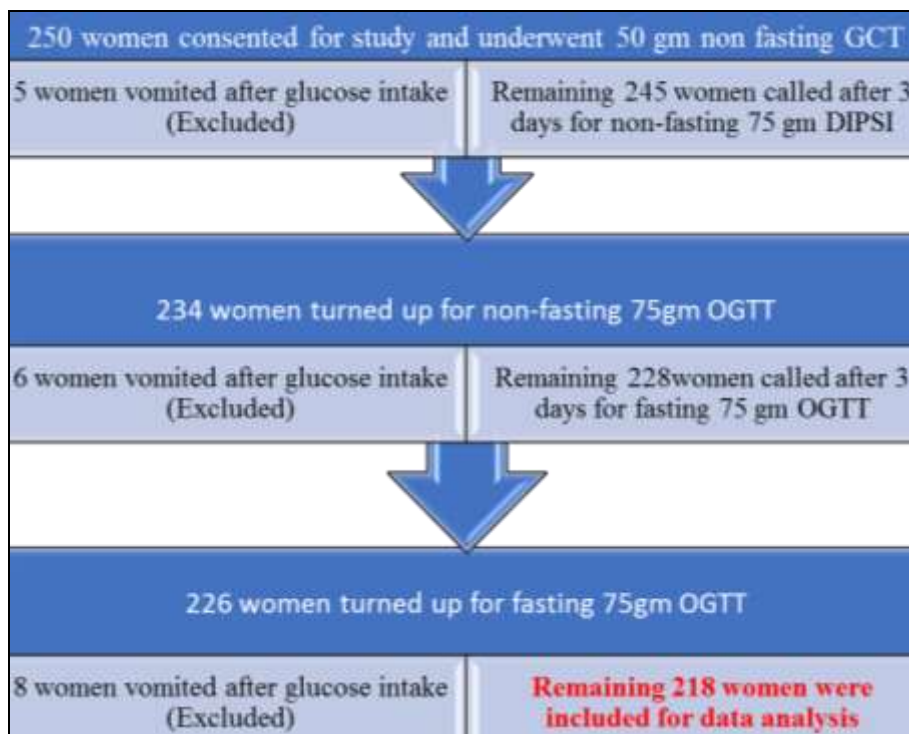


Fig 1: Flowchart of study procedure.

The mean age of the study cohort was 24.64 ± 3.82 years (median 24, interquartile range 18– 38 years). The majority of women in the study group were aged between 21 and 25 years. The mean BMI was 23.23 ± 1.93 kg/m² (median 23.2, interquartile range 18.5–28.3) and mean gestational age, $26.15 \pm$

1.27 weeks (median 26, interquartile range 24–28). Out of 218, women 18 (8.3%) had family history of diabetes mellitus. Out of these 18 women, 9 (50%) were positive for GDM. Three (1.4%) women had a history of GDM in a previous pregnancy, out of which one developed GDM.

Table 3: Result of all three-screening test

Screening Criteria		Frequency	Percent
GCT	Positive	25	11.5
	Negative	193	88.5
DIPSI	Positive	15	6.9
	Negative	203	93.1
IADPSG-Fasting	Positive	26	11.9
	Negative	196	89.9
IADPSG-1 h	Positive	14	6.4
	Negative	204	93.6
IADPSG-2h	Positive	5	2.3
	Negative	213	97.7
	Total	218	100

In the present study, twenty-seven (12.38%) were diagnosed as having GDM using the IADPSG criteria (IADPSG positive group). The majority of women in the IADPSG positive group (26 out of 27) were having fasting glucose level ≥ 92 mg/dl,

whereas one hour and two-hour samples were positive in 14 and 5 women, respectively. Using GCT criteria, twenty-five (11.46%) women were found to have GDM, whereas using DIPSI criteria, fifteen (6.8%) women were identified as having

GDM. Using all these criteria, we could identify a total of 40 women as having positive results for GDM screening (Table 3). There were no differences in age (28.15 ± 4.63 vs. 27.48 ± 3.95

vs 29.33 ± 4.08 years) and BMI (25.10 ± 1.79 vs. 24.09 ± 1.76 vs 24.89 ± 1.84 kg/ m²) between the women diagnosed with GDM using the IADPSG, GCT and/or DIPSI criteria.

Table 4: Distribution of positive case among study population.

	Positive	Percentage
IADPSG alone	11	28%
GCT alone	10	25%
DIPSI alone	2	5%
IADPSG & GCT	4	10%
IADPSG & DIPSI	2	5%
GCT & DIPSI	1	3%
Common in All	10	25%

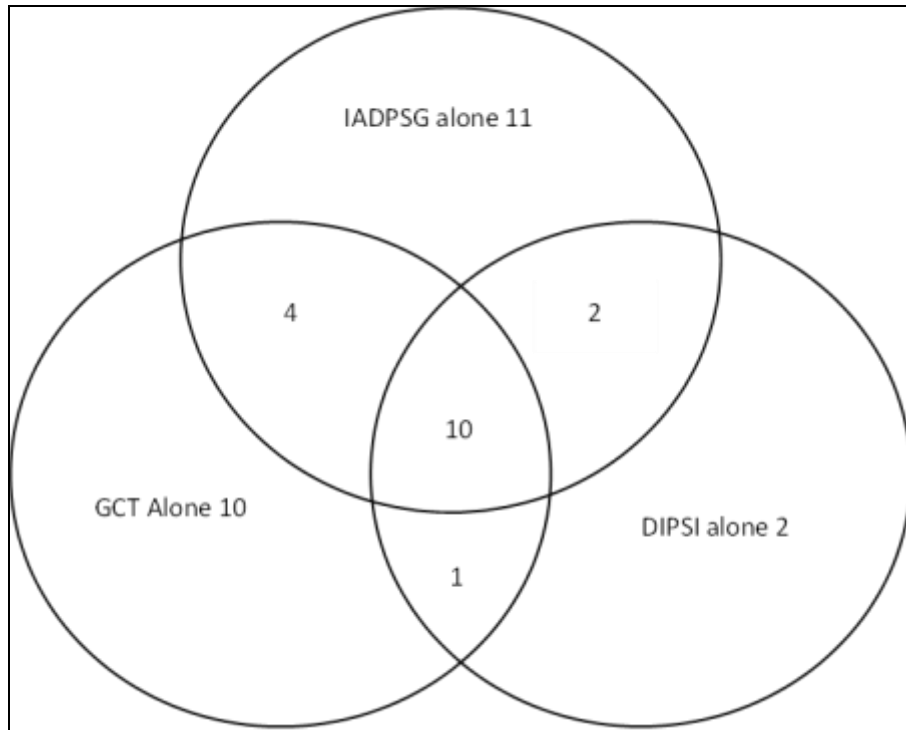


Fig 2: Venn diagram showing distribution of number of women diagnosed as having GDM by all three criteria.

Of the 27 women identified to have GDM by the IADPSG criteria, only 14 (51.85%) women were diagnosed by the GCT non-fasting criteria and 12 (44.44%) by the DIPSI criteria. Conversely, of 25 women diagnosed with GDM by the GCT non-fasting criteria, only 14 (56%) cases were diagnosed by the IADPSG criteria and 11 (44%) by the DIPSI criteria. Of the 15 women (6.8%) diagnosed with GDM by the DIPSI criteria, only 12 women (80%) were diagnosed by the IADPSG criteria and 11 (73.33%) by GCT non-fasting criteria. Only 10 women were

identified by all three (Table 4, Figure 2). Table 5 show that, when compared to the IADPSG criteria, the GCT criteria (i.e., using the 140 mg/dl cut point) had a sensitivity of 51.85% and a specificity of 94.244%. Table 6 shows that in comparison with the IADPSG criteria, the sensitivity of the DIPSI criteria was 44.44%, while the specificity was 98.43%. On comparison of DIPSI with respect to 50g non-fasting GCT, the sensitivity of DIPSI was 44% with a specificity of 97.9% (Table 7).

Table 5: Comparison of GCT criteria with IADPSG criteria.

		IADPSG							
		Positive	Negative	Total	Sensitivity	Specificity	PPV	NPV	Accuracy
GCR	Positive	14	11	25	51.9%	94.2%	56.0%	933%	89.0%
	Negative	13	180	193					
Total		27	191	218					

Table 6: Comparison of DIPSI criteria with IADPSG criteria.

		IADPSG							
		Positive	Negative	Total	Sensitivity	Specificity	PPV	NPV	Accuracy
DIPSI	Positive	12	3	15	44A%	98.4%	80.0%	92.6%	913%
	Negative	15	188	203					
Total		27	191	218					

Table 7: Comparison of DIPSI criteria with GCT.

		GCT							
		Positive	Negative	Total	Sensitivity	Specificity	PPV	NPIT	Accuracy
DIPSI	Positive	11	4	15	44.0%	97.9%	73.3%	93.1%	91.7%
	Negative	14	189	203					
Total		25	193	218					

Discussion

Females with GDM are at an increased risk of adverse maternal and perinatal outcomes [2]. They and their children are also at increased risk of future diabetes, therefore there are two generations at risk [2].

The high prevalence of DM and genetic predisposition to it among Asians, particularly in Indian women, predisposes females to develop GDM. So, there is a need for cost-effective universal screening and diagnostic methods. The Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study demonstrates that maternal hyperglycaemia even at a level below that diagnostic of DM is associated with an increased rate of maternal, fetal and neonatal complications. This also has a direct impact on the developing fetal pancreas and remains a risk factor for developing DM in the future [6].

The Diabetes in Pregnancy Study Group of India (DIPSI) has laid down guidelines for the diagnosis of GDM and proposes that the OGTT can be performed in a non-fasting state. The DIPSI guidelines further suggest that a non-fasting OGTT using a 2-h VPG value of 140 mg/dl (7.8 mmol/l) can be used as a single-step, definitive, screening and diagnostic test for GDM.

The present study was undertaken to compare the efficacy of DIPSI, IADPSG and 50 gm non-fasting GCT criteria as a screening test for gestational diabetes mellitus in Indian patients. This study shows that the non-fasting OGTT has poor sensitivity compared to both the 50gm non-fasting GCT (44%) and the IADPSG criteria (44.4%). Thus, the current DIPSI guidelines of doing a single-step non-fasting OGTT using the 2-h VPG cut point of 140 mg/dl to diagnose GDM would miss 56% of women with GDM diagnosed by the IADPSG and 50 gm non-fasting GCT criteria.

Admittedly, in developing countries like India, women have to travel long distances to attend antenatal clinics. Hence, it has been felt by many obstetricians and physicians that getting all pregnant women to come in a fasting state would be a great challenge [18, 19]. Thus, performing a non-fasting OGTT emerged as a logical option and this has become very popular in India. However, given that the sensitivity of the non-fasting OGTT is low, the present report suggests that it cannot be used as a single-step definitive diagnostic test.

One of the assumptions on which the DIPSI guidelines were framed was that it is difficult to get pregnant women to come on an empty stomach for a fasting OGTT. We found that 226 of 228 (99.12%) pregnant women did come back for the fasting OGTT in this study, although admittedly this was in a study mode. However, it is reasonable to assume that once women are told that they are likely to have GDM based on a screening test, the compliance rates for the second definitive OGTT would improve further due to better motivation. Another presumed advantage of the non-fasting OGTT is that the frequency of women who would vomit would be higher if the glucose drink is consumed on an empty stomach. Our data show that there was no significant difference in the number of women who vomited after fasting, compared to the non-fasting OGTT.

Based on the findings of this study, we suggest the following strategy. If a single-step screening and diagnostic test are to be used for GDM, the 75 gm OGTT has to be done in the fasting

state and the IADPSG criteria should be used. Alternatively, if it is not possible to get all pregnant women to come back in the fasting state, the well-established two-step procedure can be continued, using the 50 g glucose challenge test (GCT) as the initial screening test [20]. Those who screen positive (i.e., 1 h C 140 mg/dl) can be referred for the second step definitive OGTT done in the fasting state using widely accepted IADPSG criteria which need three samples depending on the resources available.

The IADPSG criteria, although adopted recently by a WHO expert group [13], may be difficult to adopt in some developing countries due to the shortage of trained phlebotomists, extra costs and the lack of laboratory support. Moreover, some reports from Western countries state that the use of IADPSG criteria could lead to inflated rates of GDM [21, 22].

Another review suggests that in low-resource settings where universal screening using a glucose challenge or an OGTT is not feasible, the use of fasting plasma glucose at 24–28 weeks may be a practical approach. In a study performed at 15 Chinese hospitals, if the OGTT was limited to women with fasting plasma glucose (FPG) ranging between 79 mg/dl (4.4 mmol/l) and 90 mg/dl (5 mmol/l), more than half of the pregnant women could avoid doing an OGTT. However, this approach may not apply to South Asians, who have a relatively higher prevalence of GDM. Furthermore, studies have shown that fasting plasma glucose values tend to have low sensitivity in South Asians [23, 24]. Also, as seen in the HAPO study, different sets of women were identified to have GDM by the fasting plasma glucose (8.3%), 1 h (5.7%) and 2 h (2.1%). Hence, the fasting plasma glucose alone may not be reliable for the diagnosis of GDM [25]. One of the limitations of this study is that maternal and fetal outcomes based on these recommendations are not available and these data are urgently needed. Secondly, the study participants were not randomized with the non-fasting and fasting tests which could have introduced a bias, but it is unlikely that this would have affected the conclusions drawn from the study.

Summary and Conclusion

In conclusion, the current DIPSI guidelines for India, which recommend utilizing a single-step non-fasting OGTT with a 2-h VPG cut point of 140 mg/dl as a screening and diagnostic test for GDM, may need to be reconsidered. A single-step 75-g OGTT utilizing the IADPSG criteria should be performed in the fasting state, if possible, as this is becoming more widely accepted and would aid in inter-national standardization. However, in resource-constrained settings, such as rural areas of developing countries, where getting all pregnant women to come in a fasted state may be difficult, the well-validated two-step procedure using a non-fasting 50 g GCT as the initial screening test, followed by a fasting OGTT for definitive diagnosis in those who screen positive, is an adequate alternative.

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