



COMPARISON OF DIABETES IN PREGNANCY STUDY GROUP INDIA(DIPSI) AND INTERNATIONAL ASSOCIATION OF DIABETES AND PREGNANCY STUDY GROUP (IADPSG) GUIDELINES FOR SCREENING AND DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS (GDM) IN TERTIARY CARE HOSPITAL IN KASHMIR

Obstetrics & Gynaecology

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ABSTRACT

Gestational diabetes mellitus (GDM) is the carbohydrate intolerance of variable severity with onset or first recognition during pregnancy. It is associated with the risk of adverse infant and maternal outcomes, and its early recognition can reduce these risks. There is a dilemma over the approach for diagnosis GDM. **Aim:** The aim of the study was screening and diagnosis of GDM at 24-36 weeks of gestation and to compare sensitivity and specificity of Diabetes in Pregnancy Study Group of India(DIPSI) taking International Association of the Diabetes and Pregnancy Study Groups(IADPSG) as gold standard. **Method:** A total of 432 women were screened for GDM by DIPSI with 75 g of glucose irrespective of the last meal and a week later fasting OGTT with 75 g glucose was done(IADPSG). Plasma glucose was measured using an autoanalyzer. **Results:** Out of 432 patients, 41 patients (9.5%) were diagnosed as GDM by DIPSI criteria. However, 62 patients (14.4%) were diagnosed by IADPSG criteria out of 432 patients. Sensitivity of DIPSI criteria using IADPSG criteria as gold standard is 27.4%, specificity 93.5%. **Conclusion:** The DIPSI guidelines for India as a screening and diagnostic test for GDM has poor sensitivity compared to the IADPSG criteria. A single-step 75-g OGTT using the IADPSG criteria should be done but, in resource-limited settings DIPSI, followed by fasting blood glucose level should be done so that fasting hyperglycemia is not missed.

KEYWORDS

Gestational Diabetes Mellitus, Diabetes in Pregnancy Study Group of India(DIPSI), International Association of the Diabetes and Pregnancy Study Groups(IADPSG).

INTRODUCTION:

Gestational Diabetes Mellitus (GDM) is defined as carbohydrate intolerance of variable severity with onset or first recognition during pregnancy (American College of Obstetricians and Gynecologists ACOG, 2017(a). GDM is associated with increased risk of several adverse infant and maternal outcomes, and its early clinical recognition can reduce these risks. There are several studies showing a significant reduction of these adverse effects when prompt and proper interventions were taken to diagnose and treat GDM early. Prevalence of GDM differs according to race, ethnicity, and age and body composition and also because of type of screening and diagnostic criteria used(1,2). It affect 7% of all pregnancies worldwide and in India it ranges from 6-9% in rural and 12-21% in urban area[3].

There is a dilemma over the best diagnostic approach for GDM. Approach of International Association of the Diabetes and Pregnancy Study Groups (IADPSG) is more flexible, and it recommends either the universal or the selective approach on the basis of the background prevalence of abnormal glucose metabolism in the population[2]. There is also a lack of international consistency with regard to the most sensitive and practical test to diagnose GDM. The Diabetes in Pregnancy Study Group of India (DIPSI) has laid down guidelines for diagnosis of GDM and proposes that the OGTT can be performed in a non-fasting state. One-step approach using GTT has been recommended by IADPSG based on results of the landmark study, Hyperglycemia and Adverse Pregnancy Outcomes (HAPO). IADPSG is universally accepted for diagnosis of GDM but need more blood samplings, fasting state, more laboratory support with extra cost. DIPSI has still got a place in low resource countries as it is easy, cost effective, and non-fasting test. Hence this prospective study was undertaken to ascertain the validity of DIPSI criterion to diagnose GDM as compared to IADPSG, and to know the sensitivity and specificity of DIPSI taking IADPSG as gold standard.

AIMS AND OBJECTIVES:

Screening and diagnosis of GDM at 24 to 36 weeks of gestation and to compare sensitivity and specificity of DIPSI taking IADPSG as gold standard.

MATERIAL AND METHODS:

This prospective study was conducted in the department of Obstetrics and Gynaecology, GMC Srinagar associated Lalla ded Hospital over a period of one and a half year. During this period on an average around 400 patients were attended each day in OPD, 50432 patients were admitted in our hospital, 34293 deliveries were conducted. During this period 432 women of gestational age 24-36 weeks were screened for gestational diabetes mellitus (GDM) by DIPSI and IADPSG criteria.

Inclusion Criteria

All antenatal women of gestational age 24-36 weeks and the women meeting the inclusion criteria were included after written informed consent was obtained.

Exclusion Criteria

Pregnant women with known pre-gestational diabetes mellitus, with chronic illness (renal, pancreatic). Women on drugs like corticosteroids, hydrochlorothiazide, anti-psychotic drugs and anti-hypertensive drugs.

Operational definition:

The DIPSI criteria:

It defines GDM as those cases who have a single blood glucose value of more than or equal to 140 mg/dl g taken 2 h after 75 g glucose load, given irrespective of fasting or non-fasting state.

The IADPSG criteria:

It defines GDM as fasting blood glucose more than or equal to 92 mg/dl or 1-h blood glucose following a 75 g oral glucose load more than or equal to 180 mg/dl or 2-h blood glucose following 75 g glucose load more than or equal to 153 mg/dl.

Methodology:

The study was done on pregnant women of gestational age 24-36 weeks in both outpatient and inpatient department. A detailed history was taken, general examination and obstetric examination done. Routine investigations were done. Informed consent for participation was taken during initial assessment. A standard proforma was used to record the data.

DIPSI with 75 g of glucose was done irrespective of last meal. Single step by giving 75 mg of oral anhydrous glucose in 300 ml of water

whether in fasting or non- fasting state and irrespective of last meal. Solution intake should be completed within 10 min. If vomiting occurred before 30 mins of the test, then the test was conducted the next day. Threshold of > 140 mg/dl was considered positive for GDM. Patients was advised to come a week later fasting (at least 8 hrs.) and OGTT with 75 g glucose was performed (IADPSG). Three venous samples fasting, one hour, two hour were drawn. GDM was diagnosed if any one of the following cut off was met i.e. ≥ 92 mg/dl (5.2 mmol/l) or 1 hour ≥ 180 mg/dl (10 mmol/l) or 2 hour ≥ 153 mg/dl (8.5 mmol/l). Plasma glucose was measured using autoanalyzer by glucose –oxidase peroxidase (GOD-POD) technique.

Statistical Analysis

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were expressed as Mean $\pm$ SD and categorical variables were summarized as frequencies and percentages. In order to establish association of GDM with various variables, Chi-square test was employed. A P-value of less than 0.05 was considered statistically significant.

RESULTS:

Table 1:

AGE(YEARS)	PERCENTAGE
<20	7.2
20-24	43.8
25-29	32.9
30-34	13.0
>35	3.2
TOTAL	100
RESIDENCE	PERCENTAGE
RURAL	64.4
URBAN	35.4
TOTAL	100
SOCIO ECONOMIC STATUS	PERCENTAGE
UPPER	0.9
UPPER MIDDLE	7.6
LOWER MIDDLE	49.3
UPPER LOWER	27.5
LOWER	14.6
TOTAL	100
PARITY	PERCENTAGE
PRIMIGRAVIDA	57.6
MULTIGRAVIDA	42.4
TOTAL	100
GESTATIONAL AGE(WEEKS)	PERCENTAGE
24-27WEEKS	37.7
28-31WEEKS	50.7
32-36WEEKS	11.6
TOTAL	100
FAMILY HISTORY	PERCENTAGE
PRESENT	21.5
ABSENT	78.5
TOTAL	100

In our study, out of 432 patients, 31 patients(7.2%) were of age <20 years, 189 patients(43.8%) were in age group of 20-24 years, 142 patients(32.9%) were in age group of 25-29 years, 56 patients(13%) were in age group of 30-34 years and 14 patients(3.2%) were of age ≥ 35 years. The mean age was 25.2 ± 4.19 years.

In our study, 249 patients (57.6%) were primigravida and 183 patients (42.4%) were multigravida and majority of patients i.e., 219(50.7%) had gestational age of 28-31 weeks followed by 24-27 weeks gestation in 163 patients(37.7%) and 32-36 weeks gestation in 50 patients (11.6%). In our study, majority of patients (64.6%) belonged to rural areas. In our study out of 432 patients, 213 patients (49.3%) belonged to lower middle class, 119 patients (27.5%) belonged to upper lower class, 63 patients (14.6%) belonged to lower class, 33 patients (7.6%) belonged to upper middle class and 4 patients (0.9%) belonged to upper class. Among 432 patients, 93 patients (21.5%) had the family history of diabetes mellitus in first degree relatives.

Table 2:

DIAGNOSIS OF GDM ACCORDING TO DIPSI CRITERIA:		
DIPSI	NUMBER	PERCENTAGE
16		

POSITIVE	41	9.5
NEGATIVE	391	90.5
TOTAL	432	100
IADPSG CRITERIA:		
IADPSG	NUMBER	PERCENTAGE
POSITIVE	62	14.4
NEGATIVE	370	85.6
TOTAL	432	100
DIAGNOSIS OF GDM BY IADPSG CRITERIA BASED ON ABNORMAL VALUES:		
GDM	NUMBER	PERCENTAGE
FASTING ALONE (>92mg/dl)	15	24.19
1 HOUR ALONE (>180mg/dl)	14	22.58
2 HOUR ALONE (>153mg/dl)	12	19.35
Any two readings elevated	16	25.80
All three elevated readings	5	8.86
TOTAL	62	100

Out of 432 patients, 41 patients (9.5%) were diagnosed as GDM by DIPSI criteria and 62 patients(14.4%) were diagnosed as GDM by IADPSG criteria and 370 patients(85.6 %) were diagnosed as normal. Among those diagnosed as GDM by IADPSG criteria, 15 patients(24.19%) has isolated fasting hyperglycemia (FPG ≥ 92 mg/dl), 14 patients (22.58%) had isolated elevated 1 hour reading, 12 patients(19.35%) had isolated elevated 2 hour reading, 16 patients (25.80%) had two elevated blood sugar readings and 5 patients(8.86%) had all three elevated readings.

Table 3: Comparison Between Iadpsg And Dipsi Criteria:

DIPSI	IADPSG POSITIVE		IADPSG NEGATIVE	
	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
POSITIVE	17	27.4	24	6.5
NEGATIVE	45	72.6	346	93.5
TOTAL	62	100	370	100

Number of patients who were positive by both DIPSI and IADPSG i.e., true positives were 17(27.4%) and number of patients who were negative by both DIPSI and IADPSG i.e., true negatives were 346(93.5%)

Number of patients who were missed by DIPSI criteria i.e., false negatives were 45(72.6%) Number of patients who were falsely taken positives by DIPSI were 24.

Table 4: Diagnostic Accuracy Of Dipsi In Predicting Gdm Taking Iadpsg As Gold Standard:

PARAMETER	VALUE	95% CI
SENSITIVITY	27.4	17.88-39.59
SPECIFICITY	93.5	90.53-95.60
PPV	41.5	27.76-56.63
NPV	88.5	84.95-91.29
ACCURACY	84.0	80.28-87.18

CI=Confidence interval

Sensitivity of diagnosing GDM by DIPSI criteria using IADPSG criteria as gold standard is 27.4%, specificity 93.5%, positive predictive value of 41.5%, negative predictive value of 88.5% and diagnostic accuracy of 84%.

Table 5: ASSOCIATION OF GDM WITH PARITY IN STUDY PATIENTS DIAGNOSED BY IADPSG					
PARITY	GDM		Non GDM		P-value
	No.	%age	No.	%age	
PRIMIGRAVIDA	23	9.2	226	90.8	0.0004*
MULTIGRAVIDA	39	21.3	144	78.7	
TOTAL	62	14.4	370	85.6	

***Statistically Significant Difference (P-value<0.05); P-value by Chi-square test**

Percentages of primigravida and multigravida women who were diagnosed as GDM were 9.2% and 21.3% respectively. Statistically significant association of GDM was seen with parity with the p value <0.005.

DISCUSSION:

India is emerging as capital of diabetes mellitus with ever increasing cases of GDM. Indian women have 11-fold increased risk of

developing glucose intolerance during pregnancy compared to Caucasian women. The recent data on the prevalence of GDM in our country was 16.55% by WHO criteria of 2 hr. PG ≥ 140 mg/dl. Given our racial predilection and dietary habits, universal screening during pregnancy has become important in our country [4]. But we face several challenges in implementing this universal screening due to inadequate infrastructure for this high screening load. So a simple, easier, cost effective, non-fasting test DIPSI is being done widely in India[5]. However recently on the bases of HAPO study IADPSG consensus panel recommended that GDM should be diagnosed based on IADPSG criteria which has more sensitivity and specificity, is more precise and accurate for diagnosing GDM and to have uniform diagnosing method all over the world. So we decided to investigate which test would be more accurate to diagnose GDM in Kashmiri population. We screened a total of 432 study patients whose mean age was 25.2 ± 4.19 years which is similar to the mean maternal age of 24 ± 3 years observed by **Mohan V et al**[6] in his study for comparison of screening of GDM by OGTT done in the non-fasting and fasting state. In our study 57.6% women screened were primigravida and 42.4% were multigravida which is similar to the study by **Rani P Reddi et al**[7] for comparison of DIPSI and IADPSG criteria for GDM diagnosis

In our study maximum women screened (49.3%) belonged to lower middle class (class III Kuppuswamy scale) which is similar to the study by **K Nirav et al**[8] done in 2019 for prevalence of GDM and associated risk factors in health centre in Gujrat.

Screening of GDM by DIPSI & IADPSG criteria was done and we observed prevalence of GDM was 9.5% with DIPSI and 14.4% based on IADPSG criteria. Prevalence data available from Indian subcontinent shows prevalence of 6.6% in western Rajasthan using DIPSI criteria done by **Kalra P et al**[9]. **Wahi P et al** [10] in Jammu found a prevalence of 6% and 6.9% respectively using the same cut off. IADPSG criteria is studied in the north Indian population in a study by **Gopalkrishnan V et al**[11] in which the prevalence of GDM was found to be 41.9%. This is much higher than any of the studies done so far. This is also much higher than the prevalence in our study. The prevalence of GDM in our study was a little higher as compared to that reported by **Wahi P et al**[10], the probable reasons may be the dietary practice in Kashmiri women.

In our study isolated fasting hyperglycemia (FPG > 92 mg/dl) is seen in 24.19% of total women diagnosed by IADPSG. **Pulkit et al** [12] in evaluating the isolated fasting glucose in diagnosis of GDM found that IADPSG criteria was better than DIPSI as the later left 23.36% women undiagnosed which could have been easily detected by IADPSG criteria and reported prevalence rate of GDM was 74.34% by DIPSI and 88.15% by IADPSG using both fasting and 2 hours plasma glucose values and by fasting value of ≥ 92 mg/dl alone 22.365% women were diagnosed. They claimed that higher rates were due to prevalence of high-risk factors in their subjects of study like advanced age, BMI, family history etc. and are also associated with poor maternal and fetal outcome.

In our study, the sensitivity of DIPSI is 27.4%, specificity is 93.5 %, positive predictive value is 41.5% and negative predictive value is 88.5 % and diagnostic accuracy is 84%. Similar sensitivity was reported in various other Indian studies. In the study done by **Mohan V et al** [13], when screening of GDM by DIPSI was compared with WHO 1999 and IADPSG, sensitivity was very low 27.7% and 22.6% respectively. **Sujoy et al** [14] identified 176(11.97%) cases of GDM by IADPSG criteria vs. 58(3.94%) by DIPSI criteria and concluded that low prevalence of GDM by DIPSI criteria is due to its low sensitivity. Thus, the current DIPSI guidelines of doing a single-step non-fasting OGTT using the 2-h VPG cut point of 140 mg/dl (7.8 mmol/l) to diagnose GDM would miss 72.6 % of women with GDM diagnosed by the IADPSG criteria.

In our study, we observed the percentage of GDM steadily increased with advancing maternal age. Statistically significant association of GDM with age with p- value < 0.01 by Chi square test. **Zargar AH et al**[24] also observed increase in prevalence of GDM with increasing maternal age with p < 0.001 . However **K Nirav et al**[16] observed no such association of maternal age with GDM in their study (p > 0.05).

We observed prevalence of GDM was more in multipara. Statistically significant association of GDM with parity with p- value < 0.05 .

Similar results were also observed by **Zargar AH et al**[15] with p < 0.006 .

CONCLUSION:

This study demonstrates that the current DIPSI guidelines for India of adopting a single-step non-fasting OGTT using a 2-h VPG cut point of 140 mg/dl (7.8 mmol/l) as a screening and diagnostic test for GDM may need to be revisited as we found poor sensitivity (27.64%) of DIPSI compared to the IADPSG criteria. DIPSI guidelines to diagnose GDM would miss 72.6 % of women with GDM diagnosed by the IADPSG criteria and it would miss about 24.19% women who had isolated fasting hyperglycemia.

Whenever feasible a single-step 75-g OGTT using the IADPSG criteria should be done in the fasting state however, in resource-limited settings, women can be tested with DIPSI and then subsequently followed with fasting blood glucose level so that fasting hyperglycemia is not missed.

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