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Diabetes in pregnancy study group of India (DIPSI) as screen method to diagnose gestational diabetes mellitus (GDM)

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Abstract

In 2019 the global prevalence of Hyperglycemia in Pregnancy (HIP) in the age group 20-49 years was estimated to be 20.4 million or 15.8% of live births. They had some form of hyperglycemia in pregnancy, of which 83.6% were due to GDM .Hence, all women should be screened for Gestational Diabetes Mellitus, even if they have no symptoms. Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. Methodology: This prospective observational study was conducted on a total of 100 pregnant women who attended antenatal clinic during pregnancy in the department of Obstetrics and Gynaecology. Following results were obtained: Mean age of cases was 24.31 years with majority of cases were in age group 21-25 years (43%) followed by 28% in age group < 20 years, 19% in age group ≥31 years, and 10% were in age group 26-30 years. Majority of cases were Hindu (80%) followed by 20% cases were Muslims. Majority of cases were in middle class (46%) followed by 40% in lower class and 14% in upper class. There were 54% cases from urban areas and 46% cases from rural cases and 60% cases were literates. Results: In majority of cases age of menarche was at 13 years (50%) followed by 37% menarche starts at 14 years of age and in 13% menarche starts at 12 years of age. The mean age of menarche was 13.2 years. The mean BMI in cases was 22.94 kg/m2, mean height was 153.79 cm and mean weight of cases was 54.46 kg. Majority of cases had normal BMI in range 18.5-24.9 (90%) followed by 10% cases were obese (25.0-29.9 kg/m2). In 50% cases were gravida of 2 and parity of 1, followed by 35% cases were primiparous, 9% had gravida of 3 and parity of 2, 6% had gravida of 4 and parity of 3. In cases having primiparity 57.14% had 2 hr. B. Sugar >140 followed by cases having gravida of 2 and parity of 1, 28.58 % had 2 hr. B. Sugar >140 and in cases having gravida of 3 and parity of 2, 14.28 % had 2 hr. B. Sugar >140. Mean cholesterol level was 187.97 mg/dl, mean Triglyceride level was 164.43 mg/dl, mean HDL level was 45.54, mean LDL level was

128.28 and mean TG/HDL level was 3.79. The mean FBS 1 hour after blood sugar was 118.39 mg/dl, mean FBS 2 hours after blood sugar was 129.73 mg/dl and mean Hb1Ac was 5.51%. There was no statistical significant difference in mean fasting blood sugar (P-value 0.54), in mean 1 hours after blood sugar (P-value 0.52) and mean in 2 hours after blood sugar (P-value 0.56) in 12-14, 14-16 and 16-18 weeks of gestational. There was no statistical significant difference in mean fasting blood sugar (P-value 0.96), in mean 1 hours after blood sugar (P-value 0.77) and mean in 2 hours after blood sugar (P-value 0.68) in 20-22, 22-24 and 24-26 weeks of gestational. In 78% cases, impaired GT (120-140) ,g/dl) followed by 15% has Normal (<120 mg/dl) and 7% has Deranged/ abnormal (>140 mg/dl) sugar level. Conclusion: DIPSI method of screening antenatal women for GDM is found to be simple, easy to perform, convenient, and well accepted by the patient. The DIPSI criteria have good diagnostic accuracy. It can be used in epidemiological studies and for diagnosis of GDM in primary care settings. The single-step approach of diagnosis makes it feasible and acceptable for use and therefore can ensure fewer noncompliance and dropouts and greater completion of the test. The findings of this study show that the prevalence of GDM is found to be much higher.

Keywords: GDM, PGDM, DIPSI, DM.

Diabetes mellitus is a chronic multifactorial metabolic disorder that requires constant medical monitoring to limit the long-term complications. This might be even seen in pregnant women exhibiting moderate to severe maternal hyperglycemia throughout her gestation, or even not been diagnosed before pregnancy, hence known a gestational diabetes mellitus (GDM/PGDM). A large body of evidence exists that support a range of interventions to improve diabetes outcomes1. To try and clarify the situations, the consensus panel of the international association of diabetes and pregnancy study groups (IADPSG) recently recommended that high risk women found to have diabetes at their initial prenatal visit should be diagnosed as having over diabetes rather than GDM2.

In extension to provide support, Ministry of Health Government of India made a mandatory screening programme of all pregnant women for Gestational Diabetes Mellitus (GDM) as part of routine antenatal package according to country's 2014 national guidelines. But its real operationalization at primary health-care level is still suboptimal. Again, Ministry of Health Government of India came up with National guidelines for diagnosing and management of GDM in February 2018. Still implementation of diagnostic procedure is unsatisfactory. One of the reasons for this inertia could be due to the incongruent opinion for the diagnosis of GDM among a few Physicians of our country. There appears to be no single strategy that is universally applicable to striking a reasonable balance in diagnosing GDM. Pragmatic local measures with careful documentation of outcomes offer the best or, perhaps more accurately, “least worst” solution. Fortunately, India has got its own guideline for diagnosing GDM. It is high time that clinicians take into consideration that “Indian Problem needs Indian Solution”3.

The basic cause of type 2 diabetes, whose prevalence is rapidly increasing worldwide, is genetic factors with the addition of such acquired factors as lack of exercise, obesity caused by a high-fat diet, stress and aging impairing insulin action, leading to the onset of diabetes. It is a fact that it is known that the incidence of GDM increases by approximately 8 times for pregnant women age 35 yrs. and over compared with women aged 25 yrs.

or under4. The quoted prevalence of GDM ranged from 1 to 14%. It depended on which population was being studied and which screening strategies and diagnostic criteria were used. The prevalence in the United Kingdom, US, and among European countries was estimated to be 5%, 3-7%, 2-6% respectively. Higher prevalence of GDM was noted in African, Asian, Indian and Hispanic women 5,6.

In the Indian context, screening is essential in all pregnant women as the 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 Plasma Glucose ≥ 140 mg/dl7. As such Universal screening during pregnancy have become important in our country. For this we need a simple procedure which is economical and feasible8.

Therefore, we aim to study efficacy of Diabetes In Pregnancy Study Group of India (DIPSI) recommended 75g oral glucose challenge test in screening and diagnosis of GDM.

Objectives

To study efficacy of Diabetes In Pregnancy Study Group of India (DIPSI) recommended 75g oral glucose challenge test in screening and diagnosis of GDM.

Math

This prospective observational study was conducted on a total number of 100 pregnant women who attended antenatal clinic during pregnancy in the department of Obstetrics and Gynaecology from March 2020 to March 2021 after approval of ethical committee of this institution and obtained written informed consent from patients.

Inclusion Criteria

- Women age between 18 – 40 years
- Women with singleton gestation
- Women with no past history of GDM or DM with family history
- Not on any treatment for other medical illness

Exclusion Criteria

- Known case of type 1 & 2 DM
- Women with multiple gestation
- Autoimmune disorders like systemic lupus erythematosis, Thyroid disorders, PCOS.

A detailed history and examination was undertaken and all the relevant data was obtained. HbA1C blood test was done at the initial antenatal visit to rule out women with pre-existing diabetes mellitus. All patients were at 24-28 gestational age and were given 75 grams anhydrous glucose irrespective of the meal and 2 hour venous blood sample was collected. Blood glucose was tested by GOD-POD (glucose oxidase peroxidise) method9. Diagnosis of impaired glucose tolerance was made when plasma glucose of ≥120-140mg/dL and diagnosis of GDM was made when the plasma glucose was >140mg/dL. Women were diagnosed as GDM and were managed appropriately. All of them were followed up until delivery. Descriptive statistics was used to calculate the mean and standard deviation to draw the conclusion of this study.

Diagnosis

Impaired glucose tolerance = ≥120-140mg/dL

GDM = >140mg/dL

Data Analysis

Data was recorded as per Performa. The data analysis was computer based; SPSS-22 was used for analysis. For categorical variables chi-square test was used. For continuous variables independent sample's t-test was used. P-value <0.05 was considered as significant.

Results

The mean age of 100 cases was 24.31 years with majority of cases were in age group 21-25 years (43%) followed by 28% in age group < 20 years, 19% in age group ≥31 years, and 10% were in age group 26-30 years. Majorities were Hindus (80%) followed by Muslims (20%), similarly, 46% were middle class followed by 40% in lower class and 14% in upper class. Urban residency cases (54%) were higher than rural residency cases (46%). Majority of 60% cases were literates and 40% cases were illiterates.

In majority of cases age of menarche starts at 13 years (50%) followed by 37% menarche starts at 14 years of age and in 13% menarche starts at 12 years of age. The overall mean age of menarche was 13.2 years. The mean BMI of cases was 22.94 kg/m2, mean height was 153.79 cm and mean weight of cases was 54.46 kgs. However, majority of cases had normal BMI in a range from 18.5-24.9 (90%) followed by 10% cases were found to be obese (25.0-29.9 kg/m2).

In 50% of cases, gravida of 2 and parity of 1 were found, followed by 35% cases were primiparous, 9% had gravida of 3 and parity of 2, 6% had gravida of 4 and parity of 3. In cases having primiparity 57.14% had 2 hr. B. Sugar >140 followed by cases having gravida of 2 and parity of 1, 28.58 % had 2 hr. B. Sugar >140 and in cases having gravida of 3 and parity of 2, 14.28 % had 2 hr. B. Sugar >140. Mean cholesterol level was 187.97 mg/dl, mean Triglyceride level was 164.43 mg/dl, mean HDL level was 45.54, mean LDL level was 128.28 and mean TG/HDL level was 3.79. The mean FBS 1 hour after blood sugar was 118.39 mg/dl, mean FBS 2 hours after blood sugar was 129.73 mg/dl and mean Hb1Ac was 5.51%.

The mean fasting blood sugar was 86.62 mg/dl in 12-14 period of gestation followed by 86.52 mg/dl in 14-16 periods of gestation and 86.63 mg/dl in 16-18 gestation period. There was no statistically significant difference in mean fasting blood sugar (P-value 0.54), in mean 1 hours after blood sugar (P-value 0.52) and mean in 2 hours after blood sugar (P-value 0.56) in 12-14, 14-16 and 16-18 weeks of gestational. There was no statistically significant difference in mean fasting blood sugar (P-value 0.96), in mean 1 hours after blood sugar (P-value 0.77) and mean in 2 hours after blood sugar (P-value 0.68) in 20-22, 22-24 and 24-26 weeks of gestational. Impaired GT (120-140),g/dl) was observed in 78% of patients, followed by 15% had Normal (<120 mg/dl) and 7% had Deranged/ abnormal (>140 mg/dl) sugar level.

Table 1: Demographic Information of Patients

Age	**Frequency**	**Percent**
Total	100	100.0
<20	28	28.0
21-25	43	43.0
26-30	10	10.0
≥31	19	19.0
mean± SD	24.31±5.23	17-36
Religion	**Frequency**	**Percent**
Hindu	80	80.0
Muslims	20	20.0
Other	0	0
Socioeconomic status	**Frequency**	**Percent**
lower	40	40.0
Middle	46	46.0
Upper	14	14.0
Residency	**Frequency**	**Percent**
Rural	46	46.0
Urban	54	54.0
Literacy	**Frequency**	**Percent**
Illiterate	40	40.0
Literate	60	60.0

Table 2: Clinical Information of Patients

Age at menarche		Frequency	Percent
Total		100	100.0
12.00		13	13.0
13.00		50	50.0
14.00		37	37.0
Mean±SD		13.2400±0.66848	
Mean±SD	Height	153.7900±5.95148	
	Weight	54.4600±5.77424	
	BMI	22.9450±1.96969	
BMI		**Frequency**	**Percent**
18.5-24.9		90	90%
25.0-29.9		10	10%
Obs History		**Frequency**	**Percent**
G2P1		50	50.0
G3P2		9	9.0
G4P3		6	6.0
Primi		35	35.0
Obstetric History		**2 hr. B. Sugar >140**	**Percentage**
Primi		4	57.14
G_2P_1		2	28.58
G_3P_2		1	14.28

Table 3: Biochemical Analysis of Patient's Serum Sample

Lipid profile	Mean	Std. Deviation
Cholesterol	187.9754	53.61174
Triglyceride	164.4340	75.64473
HDL	45.5440	6.74807
LDL	128.2840	27.09477
TG/HDL	3.7948	2.11571
Blood sugar	**Mean**	**Std. Deviation**
FBS	91.94	5.52
FBS 1 hour after blood sugar	118.39	7.20
FBS 2 hours after blood sugar	129.73	7.62
Hb1Ac	5.51	0.51

Table 4: Correlation between Pog At 1st Visit (In Weeks) And 1st Follow-Up (In Weeks) And Blood Sugar

Correlation between POG at 1st visit (in weeks) and blood sugar		N	Mean	Std. Deviation	P value
FBS	12-14	39	86.62	4.49	0.54
	14-16	33	86.52	4.44	
	16-18	28	86.63	4.54	
1 hours after BS	12-14	39	118.49	7.14	0.52
	14-16	33	118.40	7.19	
	16-18	28	118.63	7.26	
2 hours after BS	12-14	39	132.43	9.27	0.56
	14-16	33	132.25	9.38	
	16-18	28	132.28	9.53	
Correlation between POG at 1st follow-up (in weeks) and blood sugar		**N**	**Mean**	**Std. Deviation**	**P value**
FBS	20-22	27	86.54	4.45	0.96
	22-24	32	86.59	4.48	
	24-26	41	86.57	4.49	
1 hours after BS	20-22	27	118.49	7.18	0.77
	22-24	32	118.41	7.15	
	24-26	41	118.66	7.15	
2 hours after BS	20-22	27	132.40	9.31	0.68
	22-24	32	132.29	9.34	
	24-26	41	132.31	9.38	

Table 5: Dipsi Wise Distribution

FINAL DIAGNOSIS	NO OF CASES	PERCENTAGE
Normal (<120 mg/dl)	15	15%
Impaired GT (120-140) ,g/dl)	78	78%
Deranged/ abnormal (>140 mg/dl)	7	7%

Discussion

The effectiveness of glucose-challenge tests in the non-fasting state for screening and diagnosing GDM has long been a matter of debate. The ADA recommends only selective screening for GDM. Selective screening by risk factors such as woman's age, ethnicity, and BMI may miss some patients with GDM in the lower risk category, whereas more such patients may be diagnosed in the higher risk category. The reason for universal screening for GDM is to try and reduce the number of pregnant women undergoing OGTTs. A universal screening protocol requires the consideration of patient comfort, cost, and the risk of missing the diagnosis. The current ACOG recommendation of universal screening is a more practical approach but it advocates universal screening using two-step methods **Khan et al (2018)10**. In the Indian population, where there are challenges of accessibility to test centers, a test that requires a fasting state is often not feasible. Therefore, a one-step test with acceptable diagnostic accuracy is desirable, particularly in primary health-care settings. A one-step test that requires less training and which can be administered in the community using simple instruments such as a glucometer is beneficial to ensure that a larger population is covered for the screening of GDM **Balagopalan et al (2021)11.**

In our study Mean age of cases is 24.31 years with majority of cases are in age group 21-25 years (43%) followed by 28%in age group < 20 years, 19% in age group ≥31 years, and 10% are in age group 26-30 years. The mean BMI in cases is 22.94 kg/m2 with Majority of cases has normal BMI in range 18.5-24.9 (90%) followed by 10% cases are obese (25.0-29.9 kg/m2) , mean height is 153.79 cm and mean weight of cases is 54.46 kg.

Saxena et al (2020)12 found mean age of study participants was 23.74±4.02, minimum age was 18 years and maximum age was 34 years. The mean of pre-pregnancy body mass index (BMI) was 22.82±3.52 kg/m2, minimum BMI was 16 Kg/m2 and maximum was 33 Kg/m. **Rashmi and Anusha (2016)13** found mean age of study population was 23.65±3.61 years. In **Seshiah et al (2008) (Rashmi and Anusha)13** study it was observed that age ≥25yrs, BMI ≥25kg/m2 and family history of diabetes were significantly associated with the prevalence of GDM. **Polur et al (2016)14** found mean age of the 149 women was 23±5.1years, meanBMI22.6±4kg/m. **Khan et al (2018)10** reported mean age and body mass index (BMI) of the patients were 24.26±3.75 years and 20.7±3.07 kg/m2. **Rudra and Yadav(2019)15** reported mean age 23.86 years) and more than 70% from 21 years to 26 years. 73.8%, with normal body mass index (BMI), overweight 12.4%, obese 7.2%, and underweight cases consisted of 6.6%. **Balaji et al (2011)16** found mean maternal age of the 1 463 pregnant women was 23.60 ± 3.32 years and BMI was 21.5 ± 4.06 kg/m2.

Majority of cases are Hindu (80%) followed by 20% cases are Muslims. Majority of cases are in middle class (46%) followed by 40% in lower class and 14% in upper class. There are 54% cases are from urban areas and 46% cases from rural cases. There are 60% cases are literate and 40% cases are illiterate cases.

The mean age of menarche is 13.2 years with majority of cases age of menarche starts at 13 years (50%) followed by in 37% menarche starts at 14 years of age and in 13% menarche starts at 12 years of age. In 50% cases gravida of 2 and parity of 1, followed by 35% cases are primiparous, 9% has gravida of 3 and parity of 2, 6% has gravida of 4 and parity of 3.

In cases having primiparity 57.14% has 2 hr. B. Sugar >140 followed by In cases having gravida of 2 and parity of 1, 28.58 % has 2 hr. B. Sugar >140 and in cases having gravida of 3 and parity of 2, 14.28 % has 2 hr. B. Sugar

>140. **Balaji et al (2011)16** found that Using the DIPSI criterion of 2-h PG ≥ 7.8 mmol/L, 196 women (13.4%) were diagnosed as GDM.

Here, mean cholesterol level is 187.97 mg/dl, mean Triglyceride level is 164.43 mg/dl, mean HDL level is 45.54, mean LDL level is 128.28 and mean TG/HDL level is 3.79. The mean FBS 1 hour after blood sugar is 118.39 mg/dl, mean FBS 2 hours after blood sugar is 129.73 mg/dl and mean Hb1Ac 5.51%.. **Polur et al(2016)14** found shows the number of cases diagnosed by WHO and DIPSI criteria. 63 cases were screened by WHO out of which 6 cases were 1st diagnosed by 1 hr sample and rest of 57 cases and by 2 hr sample. By applying DIPSI to the same 63 GDM cases, 58 cases were diagnosed to have GDM. This shows that DIPSI was found to identify 58/63 (92.06%) of GDM cases identified and by WHO. If we consider the 2 hr samples out of 57 cases of WHO, 58 cases of DIPSI identified GDM (57/58) almost 98.27% cases could be 1st screened by DIPSI. If we carefully observe the 1 hr sample normal range (126 mg/dl) it is diabetes range outside the pregnancy but not IGT or GDM. The reason for those 6 cases diagnosed 1st by 1 hr seems to be over diagnosed by WHO criteria. **Khan et al (2018)10** suggest that Non-fasting OGTT causes the least disturbance to a pregnant woman's routine activities. Even if the DIPSI test is to be repeated in each trimester, the cost of performing DIPSI procedures will be less than the cost of performing any other diagnostic procedures because it requires little preparation, without requiring the prior interposition of the screening test. DIPSI has been proven to be a suitable test with higher sensitivity than WHO-IADPSG criteria in consonance with this study.

There is no statistically significant difference in mean fasting blood sugar (P-value 0.54), in mean 1 hours after blood sugar (P-value 0.52) and mean in 2 hours after blood sugar (P-value 0.56) in 12-14, 14-16 and 16-18 weeks of gestational at1st visit. And, similarly, There is no statistically significant difference in mean fasting blood sugar (P-value 0.96), in mean 1 hours after blood sugar (P-value 0.77) and mean in 2 hours after blood sugar (P-value 0.68) in 20-22, 22-24 and 24-26 weeks of gestational at 1st follow-up.

Zhu et al (2013)17 showed that not all women with FPG ≥92 mg/dl (5.1 mmol/l) in the first trimester developed GDM during 24–28 weeks. This author have shown that FPG at first trimester was not consistent with FPG at 24–28 weeks since less than one third of women maintained ≥92 mg/dl (5.1 mmol/l) between first trimester and 24–28 weeks. However, they do accept that doing an FPG at first visit could be useful in diagnosing undiagnosed overt diabetes. Here, in 78% cases has Impaired GT (120-140 g/dl) followed by 15% has Normal (<120 mg/dl) and 7% has Deranged/ abnormal (>140 mg/dl) sugar level.

In **Rashmi and Anusha (2016)13** study out of 200 women subjected to DIPSI recommended 75grams of OGTT 38 %, 40% and 22 % had normal, impaired and abnormal OGCT results, respectively. This proves that DIPSI method detected a greater number of cases with GDM. **Polur et al(2016)14** found out of 149 found pregnant women 63 (42.28%) were diagnosed to have GDM using the WHO 1999 criteria whereas 58 (34.89 %) women were diagnosed to have GDM using the DIPSI criteria. **Khan et al (2018)10** reported that Of the 200 women, 15.5%, tested positive with the DIPSI criteria, and 10.5% tested positive in the 100 gm OGTT as per the CCC. The 169 women who initially tested negative with the DIPSI criteria continued to be negative on repeat testing with the DIPSI and GTT at 24-28 weeks POG. In **Balagopalan et al (2021)11** study the prevalence of GDM was found to be 13% by DIPSI criteria. **Wahi et al (2011)18** also documented the advantages of adhering to

DIPSI guidelines in the diagnosis (2-h PG ≥ 7.8 mmol/L) and management of GDM for a significantly positive effect on pregnancy outcome.

Hence, the policy of not treating women with 2-h PG ≥ 7.8 mmol/L amounts to deliberately exposing the pregnant mothers to unphysiological glycemic level despite our extensive knowledge of the benefits of treatment of mild hyperglycemia during pregnancy19-22.

DIPSI is one step method that has advantage of simplicity in execution, more patient friendly, accurate in diagnosis and close to international consensus. However, in low resources set up and in rural areas where it is not feasible to carry out the above-mentioned screening program then DIPSI is recommended as a one-step glucose value testing with least disturbance to patient's routine activities and may still be valuable keeping in mind the low sensitivity and diurnal variation **(Rani and Begum)23**.

Conclusion

In conclusion, DIPSI method of screening antenatal women for GDM is found to be simple, easy to perform, convenient, and well accepted by the patient. The DIPSI criteria has good diagnostic accuracy. It can be used in epidemiological studies and for diagnosis of GDM in primary care settings. The single-step approach of diagnosis makes it feasible and acceptable for use and therefore can ensure fewer noncompliance and dropouts and greater completion of the test. The findings of this study show that the prevalence of GDM is found to be much higher. A large multicentric study is necessary to substantiate our observation. Screening and diagnosis of GDM and treating it effectively not only prevent adverse maternal and perinatal outcome but also future diabetes in both mother and child. After reviewing all the related articles on GDM, one important aspect which comes to mind is that the Indian population is diverse and variable, hence judging international criteria on Indian population may not be conclusive. So we need further comparative study on different diagnostic criteria in relation to pregnancy outcomes.

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