Original Research Paper

Obstetrics and Gynaecology

COMPARATIVE STUDY OF TWO SCREENING AND DIAGNOSTIC METHODS- INTERNATIONAL ASSOCIATION OF DIABETES AND PREGNANCY STUDY GROUP(IADPSG) WITH DIABETES IN PREGNANCY STUDY GROUP INDIA(DIPSI) IN SECOND TRIMESTER OF PREGNANCY.

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ABSTRACT

BACKGROUND AND OBJECTIVES: GDM is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (1). The prevalence of GDM varies, broadly based on the diagnostic criteria applied and the ethnic group studied. As Indian ethnicity is at high risk for GDM all antenatal women should undergo universal screening.
Incidence of GDM in India is 1-14%. There is no international agreement on the screening and diagnostic criteria for GDM. It is important to diagnose early and treat to prevent these complications. The present study was done to compare Diabetes in Pregnancy Study Group India (DIPSI) with International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria for diagnosis of GDM and to assess the validity of these methods.
METHODOLOGY: This is a comparative study which included 198 patients undergoing DIPSI and IADPSG methods to diagnose GDM in second trimester of pregnancy, who fulfilled the inclusion and exclusion criteria in the in-patient Department of obstetrics and gynecology, Santosh hospital, Bangalore, 'between September 2017 to May 2019. Both the test were compares on same group of people. The relevant investigations were done. Sensitivity and specificity of each test was evaluated.
RESULT: Prevalence of GDM in our study population was 14.1% according to IADPSG criteria and 8.1% according to DIPSI criteria and we found higher sensitivity of IADPSG 50.0% compared to 28.6% of DIPSI
CONCLUSION: we suggest IADPSG criteria is better compared to DIPSI criteria since it is more precise and accurate with high sensitivity compared to DIPSI in our study population.

KEYWORDS : GDM,DIPSI,IADPSG,OGTT

INTRODUCTION-
The prevalence of GDM in India varies from 3.8 to 21% (2). GDM is emerging as a public health problem (3).Gestational diabetes mellitus is defined as glucose intolerance with onset or first recognition during pregnancy (1). Currently GDM is diabetes that is diagnosed in the second or, more commonly, third trimester and is distinct from type1 and type 2 diabetes (ADA 2016a). In India alone, GDM complicates almost 4 million pregnancies yearly, representing large subgroup of population at high risk for adverse perinatal morbidity and mortality if left improperly managed (3).

In GDM two generations are at risk of developing diabetes in later life (4).

Inspite of plenty of research papers over the years, still lot of controversies remain, regarding type of screening, which diagnostic test to follow and ideal cutoff level. India is emerging as capital of diabetes mellitus, so number of women with GDM is also raising, hence the need for this study. Screening becomes important as women with GDM are often asymptomatic.

IADPSG recommendations-
In 2010, the IADPSG proposed a new set of diagnostic criteria for GDM, based on the results of the HAPO study, thus association of maternal glucose concentration with the risks for birth weight, cord C-peptide and % neonatal body fat to be above the 90th percentile.

An OR of 1.75 was set by the IADPSG consensus panel as a threshold to define the diagnostic criteria. The values that correspond to this OR are 92, 180, and 153 mg/dl for fasting, one-hour, and two-hour OGTT plasma glucose concentrations, respectively. The diagnosis of GDM is made if any one value is altered during a 75g OGTT. The incidence of GDM was found 17.8%in the overall population according to HAPO study.

Table 8 – GTT values according to different criteria

	NDDG (plasma) 100g ogtt	Carpenter and Coustan (whole blood)100 g ogtt	Carpenter and Coustan(plasma) 100g ogtt	O'Sullivan (whole blood)100g ogtt	IADPSG (75g ogtt)
Fasting	105	80	95	90	≥ 92
1 hour	190	155	180	165	≥ 180
2 hours	165	130	155	145	≥ 153
3 hours	145	120	140	125	

IADPSG recommends that fasting plasma glucose (FPG) or glycosylated hemoglobin (HbA1C)to be done for the diagnosis of overt diabetes during pregnancy and to differentiate it from GDM.

FPG 126 mg/dl or more and HbA1c 6.5% or more are cut-off for diagnosis of overt diabetes. Women with 92≤ FPG <126 mg/dl are diagnosed with GDM, while those with FPG<92 mg/dl should undergo a 75 g OGTT at 24 to 28 weeks of gestation.

Diabetes in Pregnancy Study Group – India (DIPSI) (6)
"A one step procedure with a single glycemic value", to diagnose GDM in the community. In the antenatal clinic, a pregnant woman after undergoing initial clinical examination is given a 75-g oral glucose load, without regard to the time of the last food. A venous blood sample is collected at 2 hours for estimating plasma glucose by the GOD- POD method.

GDM is diagnosed if 2- hour plasma glucose is ≥ 140 mg/ dl.

Advantage of DIPSI-
• Causes least disturbance in a pregnant woman's routine activities.
• Simple, easier and convenient for antenatal wome.
• Serves as both screening and diagnostic procedure.

AIMS AND OBJECTIVES-
This study is done to find out effective screening test, which serves both as a screening as well as a diagnostic tool for gestational diabetes mellitus.

1.To compare the sensitivity and specificity of IADPSG criteria with DIPSI test to diagnose4 gestational diabetes mellitus, in second trimester.
2.To know the prevalence of GDM in study population.

MATERIALS and METHODS
• 2nd trimester study is a randomized prospective comparative study between the IADPSG and DIPSI method for the screening and diagnosis of GDM in pregnancy. This study was conducted in the Department of obstetrics and gynecology, Santosh hospital, Bangalore Between September 2017 to May 2019.

INCLUSION CRITERIA: Pregnant women attending the antenatal clinic at Santosh Hospital between 24 weeks to 28 weeks of pregnancy irrespective of maternal age and gravidity and the presence or absence of clinical or historic risk factors of Gestation Diabetes Mellitus are considered for the inclusion in the study.

EXCLUSION CRITERIA:
• Diabetes mellitus diagnosed before pregnancy.

- History of intake of drugs that affect glucose metabolism like corticosteroids.

PROCEDURE FOR THE STUDY
In second trimester, they were asked to first undergo 75gms oral glucose challenge test by DIPSI procedure. They were all requested to come within one week on an empty stomach for the 75gms Oral glucose tolerance test by IADPSG procedure.

75 GRAMS 2 HOUR GLUCOSE CHALLENGE TEST(DIPSI)
- Should be done preferably in the morning.
- Irrespective of last meal status.
- 75gms of glucose dissolved in 250 ml of water and should be drunk within 5 minutes by each woman.
- The woman is asked not to consume anything for the next twohours.
- Withdraw 2 ml of blood 2 hours after the glucose load time accurately from the ante-cubital fossa in fluoride vial.
- Send the sample to the lab as soon as possible.
- Glucose oxidase peroxidase method is used to assess the concentration of glucose in venous plasma.

75 GRAMS 2 HOUR GLUCOSE TOLERANCE TEST(IADPSG)
- Ask each antenatal woman to take 3 days of unrestricted carbohydrate diet (Minimum of 150gms of carbohydrate per day and activity)
- Avoid smoking or medication which affect the blood sugar level on the day of testing.
- Woman should come in fasting state for a minimum of 8 to 12 hrs. usually from 10 pm.
- Assessment should start by 8.30 am as glucose tolerance deteriorates later in the day.
- Collect fasting sample as soon as the woman comes 10 minutes before the glucose load.
- Each woman should be given 75gms of glucose mixed in 300ml of water and should be drunk within 5 minutes.
- The woman is asked not to eat anything for the next two hours.
- Withdraw 2 ml of blood 1 hour and 2 hours after the glucose load time exactly from the ante-cubital fossa.
- Send the sample to the lab as early as possible.
- Glucose oxidase method is used to assess the concentration of glucose in venous plasma.

OBSERVATION AND RESULTS
**Table 1– Mean BMI, FBS, DIPSI value, 1 hr. pp and mean 2ndhr. pp value for study population**
Mean BMI of study population was 25.0kg/m^2.Mean DIPSI value, FBS,1 hr. PP and2nd hr. PP are 118.0 mg/dl,84.9mg/dl,151.2mg/dl and 119.4 mg/dl respectively.

	N	Mean	SD	Median	Min.	Max.
BMI	199	25.0	3.4070	25.0	18.9	32.1
FBS	199	84.9	15.564	83	62	230
DIPSI	199	118.0	25.377	116	78	328
1st Hour PP	199	151.2	23.517	148	99	420
2nd Hour PP	199	119.4	23.389	119	84	350

Table 2 – Prevalence of GDM according to different cut off for DIPSI and IADPSG
DIPSI criteria was found to be positive in 8.0% (16) of antenatal women. Using IADPSG criteria FBS only was high in12.6%(25) antenatal women, only 1 hour. post-prandial values were high in 1.0%(2) and 2-hour pp values were high in 4.0% (8) antenatal women.

	Normal		High		Total	
	N	%	n	%	n	%
DIPSI	183	92.0%	16	8.0%	199	100.0%
FBS	174	87.4%	25	12.6%	199	100.0%
1st Hour PP	197	99.0%	2	1.0%	199	100.0%
2nd Hour PP	191	96.0%	8	4.0%	199	100.0%
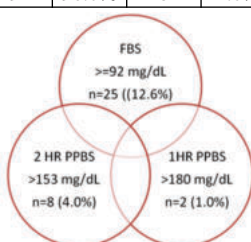
Categorization of IADPSG values – FBS value alone could diagnose more than half of IADPSG positive as GDM

Table 3 – Total number of positive and negative cases by IADPSG criteria IADPSG criteria was found to be positive in 14.1%(28) of antenatal women.

IADPSG				Total	
No		Yes			
N	%	n	%	N	%
170	85.9	28	14.1	199	100.0%

Table 4 – Comparison of IADPSG with DIPSI criteria

IADPSG	DIPSI		Total
	Normal	High	
No	162	8	170
	95.3%	4.7%	100.0%
	89.0%	50.0%	85.9%
Yes	20	8	28
	71.4%	28.6%	100.0%
	11.0%	50.0%	14.1%
Total	182	16	198
	91.9%	8.1%	100.0%
	100.0%	100.0%	100.0%

Number of both IADPSG and DIPSI positive was 08 cases, both negative were 162, IADPSG positive with DIPSI negative was 20, IADPSG negative with DIPSI positive was 08 cases.

Table 5 – Statistical parameters of IADPSG with DIPSI criteria

		95% CI
Sensitivity	50.0%	24.7 - 75.3
Specificity	89.0%	83.5 - 93.2
+LR	4.55	2.4 - 8.6
-LR	0.56	0.3 - 0.9
PPV	28.6%	13.2 - 48.7
NPV	95.3%	90.9 - 97.9
Accuracy	85.9%	

The sensitivity of IADPSG is 50.0%, specificity is 89.0%, positive predictive value is 28.6% and negative predictive value is 95.3% when compared to DIPSI.

Table 6 -Comparison of DIPSI with IADPSG

DIPSI	IADPSG		Total
	No	Yes	
Normal	162	20	182
	89.0%	11.0%	100.0%
	95.3%	71.4%	91.9%
High	8	8	16
	50.0%	50.0%	100.0%
	4.7%	28.6%	8.1%
Total	170	28	198
	85.9%	14.1%	100.0%
	100.0%	100.0%	100.0%

Number of both DIPSI and IADPSG positive in 08 cases, both negative in 162, DIPSI positive with IADPSG negative has 08, DIPSI negative with IADPSG positive has 20.

Table 32 -Statistical parameters between DIPSI and IADPSG

		95% CI
Sensitivity	28.6%	13.2 - 48.7
Specificity	95.3%	90.9 - 97.9
+LR	6.07	2.5 - 14.9
-LR	0.75	0.6 - 0.9
PPV	50.0%	24.7 - 75.3
NPV	89.0%	83.5 - 93.2
Accuracy	85.9%	
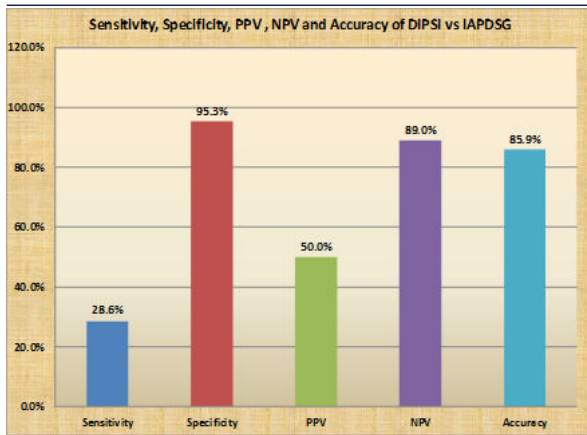
The sensitivity of DIPSI with IADPSAG was 28.6%, specificity 95.3%. Positive predictive value 50.0% and negative predictive value 89.0%.

Risk Factor
1. Age>30 yrs.
2. BMI≥25.0 kg/m^2
3. History of GDM Present

Table 7– Distribution of risk factors in positive and negative cases of DIPSI criteria

12(75.0%) of 16 women diagnosed as GDM by DIPSI criteria had age≥30 years year or BMI≥25 kg/m^2 or previous history of GDM as a risk factor.

DIPSI	Risk Factors				Total
	0	1	2	3	
Normal	83	76	23	1	183
	45.4%	41.5%	12.6%	.5%	100.0%
High	4	5	7	0	16
	25.0%	31.3%	43.8%	.0%	100.0%

Total Number with Risk Factor = 12/16=75.0%

	N	%	Risk Factors
One Risk	5	31.3%	BMI≥25.0
Two Risk	7	43.8%	GDM & BMI≥25=1; Age≥30 yrs. & BMI≥25 =6
Three Risk	0	0	

Out of 12 positives by DIPSI 5(31.3%) had BMI≥25kg/m^2 and 6 women had age>30 with BMI ≥25kg/m^2 and 1 women had positive history of GDM in previous pregnancy with BMI ≥25 kg/m^2.

Table 8–Distribution of risk factors in positive and negative cases of IADPSG

19(67.9%) of 28 women diagnosed as GDM by IADPSG criteria had age≥30year or BMI≥25 kg/m^2 or previous history of GDM as a risk factor.

IADPSG	Risk Factors				Total
	0	1	2	3	
No	78	74	18	0	170
	45.9%	43.5%	10.6%	0.0%	100.0%
Yes	9	7	12	0	28
	32.1%	25.0%	42.9%	0.0%	100.0%

Total Number with Risk Factor =19/28= 67.9%

	N	%	Risk Factors
One Risk	7	25.0%	BMI≥25.0
Two Risk	12	42.9%	GDM & Age≥30 yrs.=1; Pre GDM & BMI≥25.0 = 3; Age≥30 yrs. & BMI≥25.0 =8
Three Risk	0	0	

Out of 19 positives by IADPSG 7(25.0%) had BMI≥25kg/m^2 and 8 women had age>30 with BMI ≥25kg/m^2 and 3 women had positive history of GDM in previous pregnancy with BMI ≥25 kg/m^2 and 1 women had positive history of previous GDM with age≥30 year.

DISCUSSION
This was a comparative study of DIPSI bersus IADPSG at gestational age of 24 to 28 weeks.Recently based on HAPO study IADPSG consensus panel recommended that GDM should be diagnosed based on IADPSG criteria which has more sensitivity and specificity, more precise and accurate for diagnosing GDM and to have uniform diagnosing method all over the world.

India was not included in HAPO study despite being highly crowded and high risk ethnic group. The present study was conducted with the aim of comparing the sensitivity and specificity of DIPSI and IADPSG criteria for diagnosis of GDM.

Total number of antenatal women enrolled in to the study were 199 with mean age group of study population was 26.8 year. Mean gestational age of study population was 25.8 weeks with mean BMI of 25.0 kg/m^2.43.2% were primigravida and 56.8% were multigravida.

IADPSG diagnosed total 28 women as GDM and DIPSI diagnosed total 16 women as GDM.For IADPSG to say positive FPG was positive in 25(12.6%) women, 1-hour PP value were positive in 2(1.0%)women and 2-hour PP value were positive in 8(4.0%) women. So FPG alone could diagnose more than half of women.
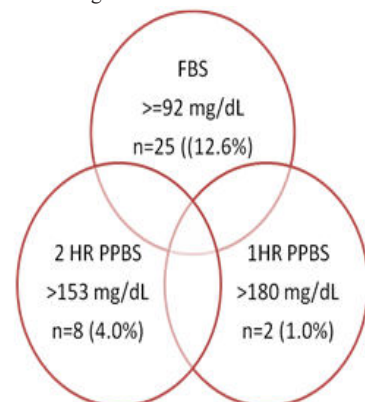
IADPSG diagnosed total 28 women as GDM and Out of them 7(25.0%) had BMI≥25kg/m^2 and 8 women had age>30 with BMI ≥25kg/m^2 and 3 women had positive history of GDM in previous pregnancy with BMI ≥25 kg/m^2 and 1 women had positive history of previous GDM with age≥30 year. So total 67.9% women of IADPSG had some risk factors.

DIPSI diagnosed total 16 women as GDM and Out of them 5(31.3%) had BMI≥25kg/m^{2}and 6 women had age>30 with BMI ≥25kg/m^2 and 1 women had positive history of GDM in previous pregnancy with BMI ≥25 kg/m^2. So total 75% women of DIPSI had some risk factors.

In the present study, out of 28 women diagnosed as GDM by IADPSG criteria, only 08 women were diagnosed by DIPSI criteria. Of the 16 women diagnosed by DIPSI ,08 women were not detected by IADPSG criteria. The prevalence of GDM in the present study was 14.1% (28) with IADPSG criteria and 8.1% (16) based on DIPSI criteria.

Both the test was positive in only 08 cases. The sensitivity of IADPSG is 50.0%, specificity is 89.0%, positive predictive value is 28.6% and negative predictive value is 95.3% when compared to DIPSI.

The sensitivity of DIPSI was 28.6%, specificity 95.3%. Positive predictive value 50.0% and negative predictive value was 89.0%. In the present study, the sensitivity of IADPSG was higher and was found to be comparatively better than DIPSI criteria for diagnosis of GDM.

DIPSI criteria which is used widely in many parts of India due to its simplicity, but it is not able to reproduce ideal sensitivity and specificity. WINGS project results found DIPSI has very low sensitivity of 22.6% and specificity of 97.8% whereas IADPSG criteria has sensitivity of 27.7% and specificity of 97.7%.

The lower sensitivity of DIPSI is believed to be due to non- fasting state when women consumes a carbohydrate meal, insulin level rises due to increased blood glucose levels and when a glucose load of 75 grams given at this point, blood glucose levels are fluctuated since insulin levels are already elevated. The sensitivity of the test drops. Therefore, WINGS project supports the international guidelines where test should be done after overnight fast.

Certainly, in developing countries like India, women have to travel long distances to attend antenatal clinics. Hence, it has been realized by many obstetricians and physicians that getting all antenatal women to come in a fasting state would be a great challange(5).

Therefore, performing a non-fasting OGTT arose as a reasonable option and this has become very widespread in India. How-ever, given that the sensitivity of the non-fasting OGTT(DIPSI) is low, the present report suggests that it cannot be used as a single-step definitive diagnostic test.

CONCLUSION

In current study DIPSI is less efficacious compared to IADPSG criteria. Our results indicate that pregnant women should have FPG as part of the diagnosis of GDM; otherwise, post challenges could lead to loss of up to a quarter of patients which is in line with IADPSG. Thus, we suggest IADPSG criteria is better compared to DIPSI criteria since it is more precise and accurate with high sensitivity compared to DIPSI. However. further studies need to be done in different parts of India to determine the applicability of the two criteria as DIPSI is practically simple, easier, non-fasting, single test suitable in low resource countries.

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