VOLUME - 11, ISSUE - 08, AUGUST - 2022 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper | Obstetrics & Gynaecology

COMPARISION OF DIAGNOSTIC ACCURACY OF NON – FASTING DIPSI AND HBAIC WITH FASTING WHO CRITERIA FOR DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS

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ABSTRACT **Background** Gestational Diabetes Mellitus [GDM] is defined as Carbohydrate intolerance with recognition or onset during pregnancy and resolves postpartum. Prevalence of GDM in India varies from 3.8 - 21% with different demography and diagnostic methods used. As early diagnosis and control of maternal hyperglycaemia plays a vital role in prevention of adverse outcomes, universal screening is almost mandatory due to high prevalence, we need a simple economical, feasible test with higher sensitivity to diagnose GDM. **Aim** To compare diagnostic accuracy of two non-fasting tests DIPSI & HBAIC and fasting WHO criteria for diagnosis of GDM. **Objectives** To compare DIPSI with WHO criteria as standard. To compare HBA1C with WHO criteria as standard **Results:** This study was done on 100 ANC cases to compare diagnostic accuracy of DIPSI & HBAIC with fasting World Health Organization Glucose Tolerance Test. Mean age of participants was 27.18±4.60 years. 39% patients were in age group of 21 to 25 years and 34% patients were in age group of 26 to 30 years. Majority (45%) of the patients were in gestational age of 26 to 30 weeks. In this study, gestational diabetes mellitus was diagnosed in 47 (47%) patients according to WHO GTT, in 48 (48%) patients according to DIPSI and in 34 (34%) patients according to Glycated Haemoglobin. Mean gestational age of patients during diagnosis of gestational diabetes mellitus was 29.21±2.84 weeks by DIPSI, 28.83±2.82 weeks by WHO GTT and 29.29±3.15 weeks by Glycated Haemoglobin. Mean blood sugar parameters of gestational diabetes mellitus women were 174.96±16.58 mg/dl by DIPSI, 173.21±17.58 mg/dl by WHO GTT and 9.41±1.91 gm% by Glycated Haemoglobin. The sensitivity of DIPSI with regard to WHO GTT was 89.36%, specificity 88.68%, positive predictive value 87.50%, negative predictive value 90.38%, diagnostic accuracy 89.00% and chi square value of 60.78. These values convey that DIPSI is as good as gold standard WHO GTT criteria. The sensitivity of Glycated Haemoglobin with regard to WHO GTT was 51.06%, specificity 81.13%, positive predictive value 70.59%, negative predictive value 65.15%, diagnostic accuracy 67.00% and chi square value of 11.51. These values convey that Glycated Haemoglobin is not as good as gold standard WHO GTT. **Conclusions:** Based on findings from this study it can be concluded that DIPSI is equally as good as World Health Organization Glucose Tolerance Test criteria in diagnosing gestational diabetes mellitus in antenatal women of south India. Since DIPSI does not require fasting it is more feasible than World Health Organization criteria. Glycated haemoglobin estimation is another test to detect diabetes mellitus which does not require fasting however its results are not close to gold standard WHO criteria unlike DIPSI.

KEYWORDS : DIPSI, GDM, Glycated haemoglobin, Pregnancy, World Health Organization Glucose Tolerance Test, WHO GTT

INTRODUCTION:

GDM remains an area of controversy, in areas including selective versus universal screening, timing of testing, choice of one-step or two-step approach, and the criteria to be used to diagnose GDM. As the prevalence of GDM is almost 11-fold higher in Indian women when compared to their Caucasian counterparts, universal screening is an essential tool in India to ensure that no case of GDM or pre-existing diabetes is missed out in spite of the increased screening costs for the government and individuals(2,3).

WHO recommends its 2006 criteria. Gestational diabetes mellitus should be diagnosed at any time during pregnancy based on any one of the following values: (1) Fasting plasma glucose = 5.1-6.9 mmol/L (92-125 mg/dL); (2) 1h post 75g oral glucose load ≥ 10.0 mmol/L (180 mg/dL) (3) 2h post 75g oral glucose load between 8.5-11.0 mmol/L (153-199 mg/dL)(2).

DIPSI method of screening is a single step procedure which overcomes practical difficulty of fasting. A woman with normal glucose tolerance can maintain euglycemia despite glucose load after meal compared to GDM patient who has impaired insulin secretion. This cascading effect is advantageous as this will not result in false positive diagnosis of GDM –(4-7).

Study Design: Prospective observational study.

Study Period: February 2020 to October 2021 in Government Victoria hospital, Department of Obstetrics & Gynaecology, Andhra Medical College, Visakhapatnam, Andhra Pradesh

Study Sample: All pregnant women between 24 - 32 weeks of gestational age attending antenatal OPD fulfilling inclusion and exclusion criteria as below:

Inclusion Criteria:
- Age 20yrs – 35yrs.
- Singleton pregnancy.
- Live fetus.
- Gestational age between 16 to 36 weeks.

Exclusion Criteria:
- Multiple Gestation
- Gestational age > = 36 weeks
- Intrauterine fetal death.
- Any other medical complications
- Pre-existing diabetes.

Sample Size: 100

Study Procedure:
After informed consent, all women attending the antenatal out-patient department were asked for detailed history and were performed thorough clinical examination. Those who satisfied the inclusion and exclusion criteria are given 75gm glucose orally in water,to be consumed within 10 min irrespective of previous meal as recommended by DIPSI. Blood sugars were measured after 2 hours. HBAIC was also

done in same sitting. All participants were asked to come after 72hr in a fasting state for WHO GTT. Blood sugar was measured in fasting state and then 2 hours after glucose. 75g OGTT and collection of blood samples were carried out by qualified medical laboratory technicians at our hospital using standard protocols. The blood sugar samples were analysed on fully automated clinical chemistry analyser AU480 (Olympus, Beckman coulter, USA) using commercially available kit provided by Randox, UK, using GOD/POD method. The HbA1C samples were analysed on fully automated clinical chemistry analyser AU480 (Olympus, Beckman coulter USA) using commercially available kit provided by Randox, UK, using immunoturbidimetry method. Diagnosis of GDM was made if 2 hours post glucose blood sugar was >140 by either test or if HBA1C > or = 6 %.

Ethical Considerations:

Prior permission was taken from Institutional Ethics Committee, Andhra Medical College, Visakhapatnam. A Written informed consent was taken from each individual of the study.

Statistical Analysis

The results were expressed as mean ± standard deviation and percentage. The sensitivity, specificity, predictive value and diagnostic accuracy between the DIPSI and HbA1c with gold standard WHO GTT were computed using Chi-square test and Pearson's correlation was used for comparison. Statistical significance was considered at $P < 0.05$. Statistical analysis was done using MS excel and SPSS.

RESULTS

100 patients were recruited in this study.

Mean age of all study participants was 27.18±4.60 years. Among these 100, 39 (39%) comprised of patients aged 21 to 25 years, 34 (34%) were aged 26 to 30 years, 25 (25%) were aged 31 to 36 years and 2 (2%) were aged < 20 years.

Table I: Age Distribution Among Study Subjects		
AGE RANGE (years)	N	%
<20	2	2
21-25	39	39
26-30	34	34
31-36	25	25

Mean gestational age on day of testing of all study participants was 25.62±5.33 weeks. Among these 100, 45 (45%) comprised of patients in GA of 26 to 30 weeks, 22 (22%) were in GA of 16 to 20 weeks, 19 (19%) were in GA of 21 to 25 weeks, and 14 (14%) were in GA of 31 to 36 weeks

Table II: Gestational Age Distribution Among Study Subjects		
GA RANGE (WEEKS)	N	%
16-20	22	22
21-25	19	19
26-30	45	45
31-36	14	14

INCIDENCE OF GDM

In this study of 100 patients, GDM was diagnosed in 47 (47%) patients according to WHO OGTT, in 48 (48%) patients according to DIPSI and in 34 (34%) patients according to HBA1C

Table III: Incidence Of GDM		
	n	%
WHO OGTT	47	47
DIPSI	48	48
HBA1C	34	34

MEAN AGE IN GDM

Mean age of patients diagnosed of GDM was 29.94±3.10 years by DIPSI, 29.72±3.01 years by WHO OGTT and 30.53±3.33 years by HBA1C.

Table IV: Mean Age (years) Of GDM Patients Diagnosed By Different Methods	
DIPSI	29.94±3.10
WHO OGTT	29.72±3.01
HBA1C	30.53±3.33

Mean Gestational Age In Gdm Diagnosed Cases

Mean GA of patients during diagnosis of GDM was 29.21±2.84 weeks by DIPSI, 28.83±2.82 weeks by WHO OGTT and 29.29±3.15 weeks by HBA1C.

Table V: Mean Gestational Age (weeks) Of GDM Patients Diagnosed By Different Methods	
DIPSI	29.21±2.84
WHO OGTT	28.83±2.82
HBA1C	29.29±3.15

Mean Blood Sugar Parameters

Mean blood sugar parameters of GDM women were 174.96±16.58 mg/dl by DIPSI, 173.21±17.58 mg/dl by WHO OGTT and 9.41±1.91 % by HBA1C.

Table VI: Mean Blood Sugar Parameters In GDM Women	
DIPSI	174.96±16.58 mg/dl
WHO OGTT	173.21±17.58 mg/dl
HBA1C	9.41±1.91 %

COMPARISON DIPSI WITH WHO GTT

Women diagnosed as GDM by WHO GTT were 47 and by DIPSI were 48. The sensitivity of DIPSI with regard to WHO GTT was 89.36%, specificity 88.68%, positive predictive value 87.50%, negative predictive value 90.38%, diagnostic accuracy 89.00% and chi square value of 60.78. The ROC curve between WHO and DIPSI covered an area of 0.903. Pearson's correlation between WHO and DIPSI was 0.632, and R2 was 0.400 ($p<0.05$).

Table VII: Chi Square Comparison Of GDM Positive By DIPSI VS WHO OGTT				
		WHO OGTT		
		+	-	
DIPSI	+	42	6	48
	-	5	47	52
		47	53	100

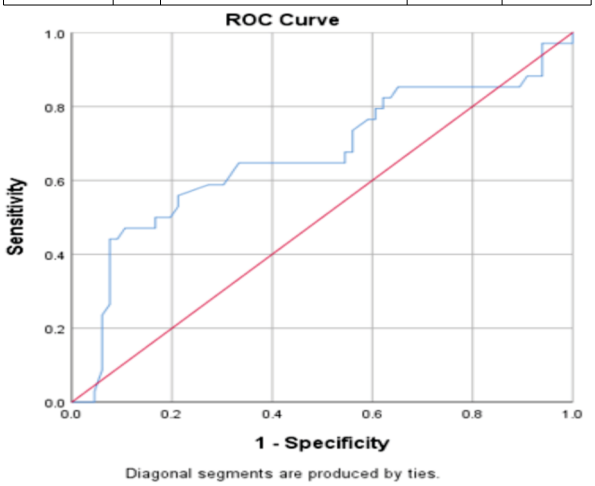

Figure I: ROC curve of DIPSI vs WHO GTT

COMPARISON HBA1C WITH WHO GTT

Women diagnosed as GDM by WHO GTT were 47 and by HBA1C were 34. The sensitivity of HBA1C with regard to WHO GTT was 51.06%, specificity 81.13%, positive predictive value 70.59%, negative predictive value 65.15%, diagnostic accuracy 67.00% and chi square value of 11.51. The ROC curve between WHO and HBA1C covered an area of 0.666. Pearson's correlation between WHO and HBA1C was 0.304, and R2 was 0.093 ($p=0.002$).

Table VIII: Chi Square Comparison Of GDM Positive By HBA1C VS WHO OGTT

		WHO OGTT		
		+	-	
HBA1C	> 7	24	10	34
	< 7	23	43	66
		47	53	100

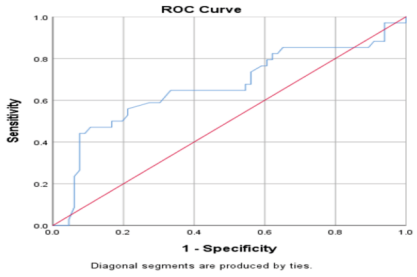

Figure II: ROC curve of DIPSI vs WHO GTT

DISCUSSION

Gestational diabetes mellitus is one of the most common medical disorder which complicates pregnancy (8). Apart from affecting pregnancy, gestational diabetes mellitus also imparts long term risk to mother and fetus (9). Early identification of gestational diabetes mellitus in pregnant women can prevent maternal and perinatal morbidity and also improves long term outcomes in mother and fetus (10). Several criteria for diagnosing gestational diabetes mellitus have been recommended by various national and international bodies. Evidence suggests that universal screening improves pregnancy outcomes compared to selective screening and that non-screening omits approximately 4% patients with gestational diabetes mellitus (11). For universal screening, World Health Organization recommends 75 grams Glucose Tolerance Test as a one-step screening and diagnostic procedure (7,12). On 14th march 2007, Government of India order recommended universal Screening at 24-28 weeks of Pregnancy with 75 grams oral glucose tolerance test. Venous blood glucose sample of 140 mg% or more is suggestive of gestational diabetes mellitus (13). One step procedure is less time consuming, economical and feasible. DIPSI procedure is cost effective, without compromising the clinical equipoise and can be continued to diagnose gestational diabetes mellitus in our country (14). Comparison with other studies (15,16)

Table IX: Comparison Of Incidence Of Gestational Diabetes Mellitus By Different Methods In This Study Vs Previous Studies

	Present Study	Saxena et al	Balagopalan et al	Mohan et al
WORLD HEALTH ORGANIZATION CRITERIA	47%	6.375%	13%	2.23%
DIPSI	48%	7.87%	14.2%	8.05%
GLYCATED HEMOGLOBIN	34%	5%	--	--

Table X: Comparison of Statistics for DIPSI Vs World Health Organization Glucose Tolerance Test and Glycated haemoglobin Vs World Health Organization Glucose Tolerance Test

	DIPSI Vs World Health Organization Glucose Tolerance Test		Glycated Haemoglobin Vs World Health Organization Glucose Tolerance Test	
Statistic	**Value**	**95% CI**	**Value**	**95% CI**
Sensitivity	89.36%	76.90% to 96.45%	51.06%	36.06% to 65.92%
Specificity	88.68%	76.97% to 95.73%	81.13%	68.03% to 90.56%
Positive Predictive Value	87.50%	76.60% to 93.74%	70.59%	56.24% to 81.76%
Negative Predictive Value	90.38%	80.32% to 95.58%	65.15%	57.59% to 72.02%
Accuracy	89.00%	81.17% to 94.38%	67.00%	56.88% to 76.08%
Chi-square = 60.7819.			Chi-square = 11.51	

Present study is first of its kind study which has compared DIPSI and Glycated Haemoglobin against World Health Organization Glucose Tolerance Test criteria as gold standard for diagnosing gestational diabetes mellitus in south Indian population.

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