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"COMPARISON OF DIAGNOSTIC ACCURACY OF NON-FASTING DIPSI AND HbA1c WITH FASTING WHO CRITERIA FOR DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS"

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ABSTRACT

Objective: 1) To study prevalence of GDM. 2) Diagnostic accuracy of DIPSI and HbA1c in detecting GDM.
Methods: 500 pregnant women with singleton pregnancy between 24-32 weeks of gestation were recruited into the study. They underwent DIPSI test and HbA1c in the same sitting. A 2-h 75-gm OGTT was repeated for all women after 72 h in fasting state (WHO criteria). GDM was diagnosed if plasma glucose was ≥140 mg/dl by either test or if HbA1C ≥6%.
Results: Of the 500 women, 34 were diagnosed as GDM by WHO criteria, 40 by DIPSI and 28 by HbA1c.Thus, the prevalence of GDM was 6.8% as per WHO criteria, 8% as per DIPSI and 5.6% by HbA1c. The sensitivity of DIPSI test was 94.12%, specificity 98.28%, diagnostic accuracy 97.95%, positive predictive value 80% and negative predictive value 99.57%. The sensitivity of HbA1c with respect to WHO criteria was 52.94%, specificity 97.85%, positive predictive value 64.29%, negative predictive value 96.61%, diagnostic accuracy 95.31%. The area under the ROC curve between DIPSI and WHO criteria was 0.989 while between HbA1c and WHO criteria was 0.923.
Conclusion: The DIPSI criteria may be recommended for diagnosing GDM. But, HbA1c does not serve as a good screening test.

KEYWORDS

GDM, DIPSI, HbA1c

INTRODUCTION:

Diabetes mellitus is a metabolic disorder that results from a defect in insulin secretion by pancreatic beta cells, insulin action or both. A consequence of this defect is hyperglycemia. Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy.[1]

GDM is the most common medical complication and metabolic disorder of pregnancy occurring in 1-14% of pregnant women depending on the population described and the criteria used for diagnosis.[2] The prevalence of GDM has increased from 4.6 % in 2006 to 8.2% in 2016 in United States.[3] The rate of increase in prevalence over the past 10 years has been the highest for Asian and African-American women.[4] A previous study of 3,674 patients across 7 cities in India estimated that the prevalence of GDM was 16.55% in India using the WHO 1999 method.[5] It is estimated that about 4 million women are affected by GDM in India at any given point of time. In urban areas the incidence of GDM is 16.2% and in rural areas it is 9.9%. In a field study in Tamil Nadu performed under the "Diabetes in Pregnancy - Awareness and Prevention project," the prevalence of GDM was 17.8% in the urban, 13.8 % in the semi urban and 9.9 % in the rural areas.[6]

Common risk factors that are associated with GDM include a family history of Diabetes Mellitus in first degree relative, higher age, overweight, history of delivery of a large baby in previous pregnancy.[7]

Normal pregnancy is associated with insulin resistance similar to that found in type 2 diabetes. Physiological resistance to insulin action during pregnancy becomes apparent in the second trimester when placental hormones that have the opposite effect of insulin on glucose metabolism increase substantially and insulin sensitivity declines progressively to term. These changes facilitate transport of glucose across the placenta to ensure normal fetal growth and development. Transfer of glucose across the placenta stimulates fetal insulin secretion and insulin acts as an essential growth hormone. Women with adequate insulin secreting capacity overcome this insulin resistance of pregnancy by secreting more endogenous insulin to maintain normal blood glucose. Women with less adequate pancreatic reserve are unable to produce sufficient insulin to overcome the increase in insulin resistance and glucose intolerance results.

Various maternal complications of GDM like polyhydramnios, preeclampsia, prolonged labor, obstructed labor, caesarean section, uterine atony, postpartum hemorrhage, infection, retinopathy etc. and fetal complications like spontaneous abortion, intrauterine death, stillbirth, congenital malformation, shoulder dystocia, birth injuries, neonatal hypoglycemia and infant respiratory distress syndrome leads to significant maternal and fetal morbidity and mortality. Prompt diagnosis of GDM is the first step towards effective management and prevention of adverse outcomes. Therefore, the need for universal screening is well recognized specially in Indian women who have 11-fold higher risk of developing GDM compared to Caucasian women.[8]

Considering the wide gap between the target and reality, a practical, cost-effective, easy and convenient screening test is required so that the women can be tested during their initial visit even in a non-fasting state as many may not return subsequently in a fasting state. The aim of this study was to compare the diagnostic accuracy of two non-fasting tests, DIPSI and HbA1c with fasting WHO criteria in diagnosing GDM.

MATERIAL METHODS:

This is a prospective study conducted in the Department of Obstetrics and Gynaecology, Government Medical College, Amritsar. The study was conducted only after approval from Institutional Ethics Committee. 500 pregnant women with singleton pregnancy attending the antenatal clinic at BNMCCC between 24-32 weeks of gestation were recruited into the study after verification of all exclusion criteria. Written informed consent was taken. Pregnant women included in the study were subjected to a 2-h 75-gm GCT in non-fasting state (DIPSI). HbA1c was also determined at the same sitting. A 2-h 75-gm OGTT was repeated for all women after 72 h in a fasting state (WHO criteria). GDM was diagnosed if plasma glucose was ≥140 mg/dl by either test or if HbA1C ≥6%. The data from the present study was systematically collected, compiled and statistically analysed to draw relevant conclusions. Data was analysed by using X^2 test. The p-value was determined finally to evaluate the level of significance. The p-value of 0.01 to 0.05 was considered significant. The results were then analysed and compared to previous studies. SPSS-22 version of software was used, released 2013, Armonk, NY: IBM Corp. ROC curve analysis was performed to explore the diagnostic accuracy of DIPSI and HbA1c in diagnosis of gestational diabetes mellitus.

RESULTS:

Out of the 500 pregnant women, 34 were diagnosed to have GDM by WHO fasting criteria. Thus, the prevalence of GDM in this study was 6.8%. While 40 were categorised to have GDM according to non-fasting DIPSI, 28 were diagnosed by HbA1c (Figure 1). Thus, the prevalence of GDM by DIPSI was 8% and as per HbA1c was 5.6%. Thus, DIPSI criteria were able to pick more patients compared to WHO criteria or HbA1c.

The mean age of total study population was 26.13+4.52 years, while that of GDM group was 27.97+6.05 years. 67.64% of GDM patients were >25 years of age. 64.7% of GDM patients has a significant past

obstetrical history. 17.65% (6) patients gave history of abortion. 29.41% (10) had history of still birth, while 17.65% (6) had history of both abortion and still birth. 20 out of 34 GMD patients had a family history of diabetes mellitus. This accounts for 58.8% while only 6.43% of non GDM group had family history of diabetes mellitus. It was observed that age >25 years, multiparity, family history of diabetes mellitus and previous history of abortion, still birth had statistically significant association with GDM. Figure 2 shows the prevalence of various risk factors in GDM groups as diagnosed by WHO criteria, DIPSI and HbA1c method.

Number of women diagnosed to have GDM by WHO criteria were 34 and by DIPSI were 40 (Table 1). The sensitivity of DIPSI with regards to WHO criteria was 94.12%, specificity was 98.28%, positive predictive value was 80%, negative predictive value was 99.57% and diagnostic accuracy was 97.95%. The mean blood glucose of the total study population was 101.81±20.86 mg/dl. In cases of GDM, the mean blood glucose by DIPSI was 166.90±16.36 mg/dl and by WHO criteria was 154.94±11.74 mg/dl. Area covered under the ROC curve (Figure 4) between DIPSI and WHO criteria was 0.989 (p=0.001).

Total number of cases of GDM detected by HbA1c was 28 (Table 2). The sensitivity of HbA1c with respect to WHO criteria was 52.94%, specificity was 97.85%, positive predictive value was 64.29%, negative predictive value was 96.61% and diagnostic accuracy was 95.31%. The mean value of HbA1c of the total study population was 4.34±1.01% while that in cases of GDM was 6.52±0.56%. Area covered under the ROC curve (Figure 5) between HbA1c and WHO criteria was 0.923 (p=0.001).

DISCUSSION:

This study compared the diagnostic efficacy of non-fasting tests DIPSI and HbA1c with fasting WHO OGTT for practical, one-step diagnosis of gestational diabetes mellitus during the first visit itself as many women may not return for a subsequent check up in a fasting state.

The prevalence of GDM in this study was 6.8%. This is similar to a study conducted by Saxena P et al in which the prevalence of GDM was found to be 6.25%.[9] According to Tripathi R et al the prevalence of GDM was 6.7%.[10] Similar findings was seen in various other studies (Table 3).

In the present study comprising of 500 pregnant women, 40 were detected to have GDM as per DIPSI. Whereas according to WHO fasting criteria 34 were diagnosed to have GDM. Of these 34 patients, 32 were categorised as GDM by DIPSI also. Thus, in comparison to WHO criteria sensitivity of DIPSI was 94.12%, specificity was 98.28%. Area under the ROC curve between WHO criteria and DIPSI was 0.989 (p value 0.001). Similar findings are seen in a study done by Saxena P et al where, out of the 800 pregnant women studied, 63 had GDM as per DIPSI. The sensitivity of DIPSI test with respect to WHO criteria was 98.04% and specificity 98.26%. The diagnostic accuracy was 98.25%. The area under the ROC curve for DIPSI was 0.988 (p<0.001) (95% confidence interval: 0.960–1.000).[9] Another study done by Anjalakshi C et al on South Indian population showed 100% sensitivity and 100% specificity of 75g, two-hour non-fasting DIPSI test when compared with the WHO OGTT for the diagnosis of GDM. They concluded that there was no significant difference between the two tests in identifying women with GDM.[11]

Another study conducted on Indian population by Sharma K et al showed similar results of 100% sensitivity and 100% specificity of non-fasting DIPSI when compared to fasting WHO criteria.[12]In the study of Badikillaya VU et al, out of 200 women, 22 were diagnosed of GDM by DIPSI criteria. This accounted for a sensitivity of 100% and specificity of 89% when compared with WHO criteria.[13] In another study done by Tripathi R et al, the sensitivity of DIPSI was 65.1% and specificity was 96.3%. The positive predictive value and negative predictive value were 56.1% and 97.7%, respectively. The diagnostic accuracy was 94.2%.[10]

In our study 28 women were found to have GDM as per HbA1c criteria. On comparing it with WHO criteria HbA1c had a sensitivity of 52.94%, specificity 97.85%, positive predictive value was 64.29%, negative predictive value was 96.61% and diagnostic accuracy was 95.31%. The ROC curve between WHO criteria and HbA1c covered an area of 0.923 (p value 0.001). In a study done by Saxena P et al, where out of the 800 pregnant women studied, total number of cases of GDM detected by HbA1c were 40. The sensitivity of HbA1c with respect to WHO criteria was 47.06%, specificity was 97.86%, positive predictive value was 60.0%, negative predictive value was 96.45% and diagnostic accuracy was 94.63%. The ROC curve between WHO criteria and HbA1c covered an area of 0.805 (p value<0.01) with 95% confidence interval (0.731–0.879). They concluded that it does not serve as a good screening test.[9]

Likewise, Lai Y et al conducted a large retrospective study among 19,261 Chinese pregnant women and deduced that the optimal cut-off point of HbA1c for GDM diagnosis was 5.0% (31 mmol/mol), which yielded a sensitivity of 60.1%, a specificity of 65.3%, a positive predictive value of 28.1% and a negative predictive value of 87.9%. There was a positive but weak correlation between HbA1c value and glucose levels of OGTT. Hence, they concluded that HbA1c offers only limited value in diagnosing GDM.[14] In another Chinese research, which included 1,959 pregnant individuals, the AUC of HbA1c to detect GDM was 0.66 (95% CI: 0.63–0.69) and the optimal cut-off point of 5.2% (33 mmol/mol) could only predict GDM with a sensitivity of 41.6% and a specificity of 81.5%.[15]

CONCLUSION:

The non-fasting DIPSI criteria may be recommended for diagnosing GDM due to its high diagnostic accuracy, sensitivity and specificity when compared to fasting WHO criteria. DIPSI has several advantages over WHO criteria as this single test serves both as a screening and diagnostic test, does not require the patient to come in fasting state and is economical too. Therefore, DIPSI is an appropriate and practical test that can be used for universal screening of pregnant women during the initial visits itself. HbA1c has good specificity but not sensitivity. It has a high negative predictive value but not positive predictive value. Therefore, HbA1c does not serve as a good screening test.

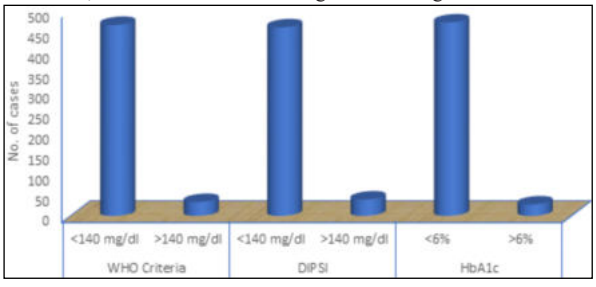

Figure 1: Prevalence Of GDM In The Study Population By Various Methods Being Studied

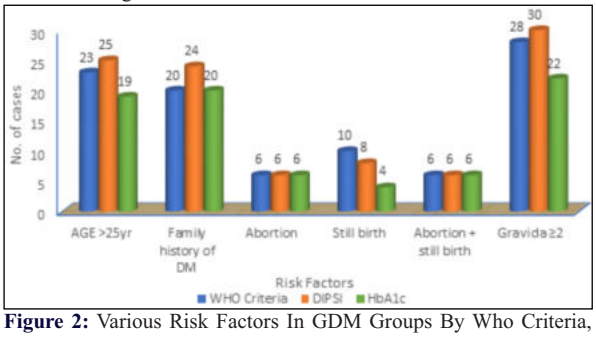

Figure 2: Various Risk Factors In GDM Groups By Who Criteria, Dipsi And Hba1c Method

Table 1 Comparison Between Who Criteria And DIPSI

DIPSI	WHO Criteria			
	<140 mg/dl		>140 mg/dl	
	No.	%age	No.	%age
<140 mg/dl	458	98.28	2	5.88
>140 mg/dl	8	1.72	32	94.12
Total	466	100.00	34	100.00

Table 2 Comparison Between Who Criteria And HbA1c

HbA1c	WHO Criteria			
	<140 mg/dl		>140 mg/dl	
	No.	%age	No.	%age
<6%	456	97.85	16	47.06
>6%	10	2.15	18	52.94
Total	466	100.00	34	100.00

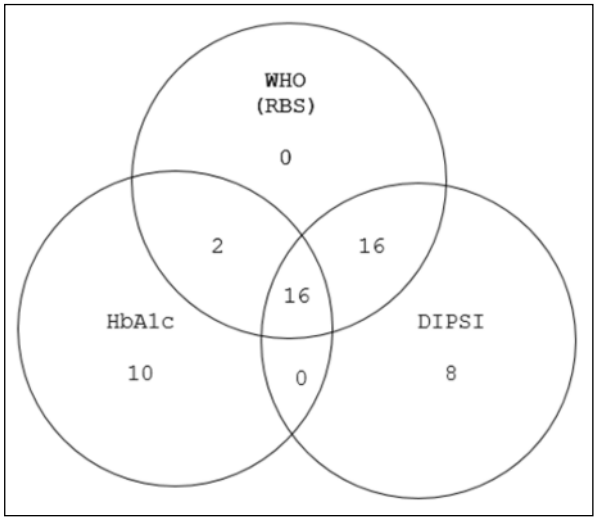

Figure 3: Distribution Of GDM Patients Among Who, DIPSI And HbA1c Group

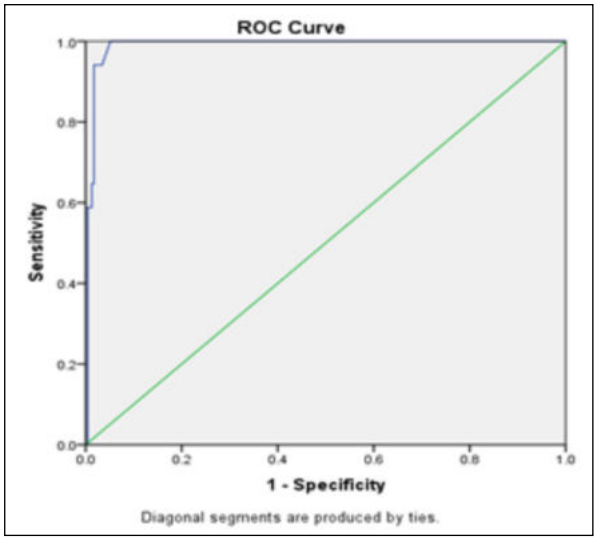

Figure 4: ROC Curve Between WHO Criteria And DIPSI

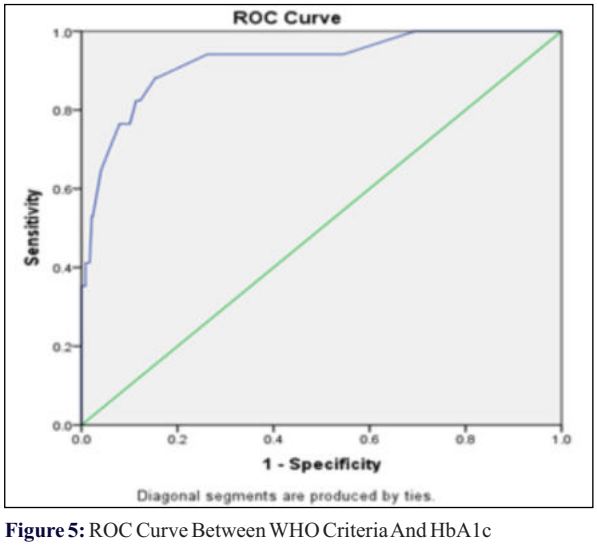

Figure 5: ROC Curve Between WHO Criteria And HbA1c

Table 3: Prevalence Of GDM Among Various Studies

Sr. No.	References	Prevalence
1	Saxena P et al[38]	6.25%
2	Tripathi R et al[39]	6.7%
3	Mohan V et al[36]	8%
4	Sharma K et al[34]	11%
5	Khalafallah A et al[46]	11.9%
6	Present study	6.8%

DISCLOSURES

1) Ethics committee approval: yes
2) Written informed consent: yes

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Conflict Of Interest: No conflict

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