

To Compare the Diagnostic Accuracy of Non-Fasting DIPSI with Fasting WHO Criterion for Diagnosis of Gestational Diabetes Mellitus

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Abstract

The aim of our study was to compare and correlate DIPSI criteria based test with conventional WHO OGTT for diagnosis of GDM. 200 healthy pregnant women attending antenatal clinic of B.P.S. Government Medical College underwent 75 gm OGTT between 24 - 28 weeks of pregnancy irrespective of their last meal on first hospital visit. After 2 hours venous blood sample was obtained and analysed. Three days later all of them were made to undergo 75 gm OGTT after an overnight fasting of 10 - 12 hours as recommended by WHO. Two blood samples, one fasting and then 2 hour after glucose load were obtained and analysed. GDM was diagnosed if fasting plasma glucose > 126 mg/dl and > 140 mg/dl of post glucose load 2 hour value by either test. Of the 200 women evaluated, 4 were diagnosed to have GDM by DIPSI alone, 8 by WHO alone and 21 by both criterion. The sensitivity and specificity of DIPSI compared to WHO99 was 72.4 % and 97.7 % respectively. The diagnostic accuracy was 94.0 %. The area under the ROC curve for DIPSI was 0.850 (p < 0.05) (95 % confidence interval: 0.751 - 0.950). The results of present study support DIPSI as a simple, convenient, economical test which can be used as both diagnostic as well as screening test with good diagnostic efficacy.

Keywords: GDM, WHO GTT, DIPSI, ACOG, NICE, ADA

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Introduction

Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy [1]. The global burden of diabetes

has increased from 135 millions in 1995 to projected 300 millions in 2025, along with that of GDM [2]. The prevalence of GDM in India varied from 3.8 to 21 % in different

parts of the country, depending on geographic locations and diagnostic methods used [3].

The importance of GDM is that two generations are at risk of developing Diabetes in the future. Women with a history of GDM are at increased risk of future diabetes, predominantly type 2, as are their children [4]. Studies have shown that there is a much higher rate of maternal and foetal complications in diabetic pregnancies as compared to normal pregnancies [5]. Therefore, universal screening is advised for early diagnosis of GDM especially for Indian women who have 11 fold higher risk of developing GDM compared to Caucasian women [6].

The conventionally used method for diagnosis of GDM is WHO criteria. This requires women to come in fasting state. It is difficult for pregnant women with morning sickness to travel fasting to antenatal clinic and wait for an additional 2 hours before eating. These adds up to other problems of rural areas like lack of trained phlebotomist, lack of standardised laboratories, transportation problems which increases the dropout percentage of pregnant women for subsequent visits.

To overcome these problems, DIPSI recommended a 75 gm GCT in non fasting state for diagnosis of GDM. This has proven to be simple, cost effective and feasible alternative for diagnosis of GDM [7]. But the universal adoption of DIPSI received setback as few recent studies have reported its poor sensitivity and specificity compared to other tests [8-10]. Although Government of India has recommended DIPSI for diagnosis of GDM in our country [11]. The aim of our study was to compare the diagnostic accuracy of non fasting DIPSI with fasting conventional WHO 1999 test for diagnosis of GDM.

Materials & Methods

This study was undertaken after approval from institutional ethical committee of B.P.S.

Government Medical College, Khanpur, Sonipat and informed consent from patient was taken. The present study was a cross-sectional study done during December 2018 to November 2019. The study population comprised of 200 pregnant women with singleton pregnancy between 24 to 28 weeks of gestation and who were previously undiagnosed with Diabetes in present or previous pregnancy.

After detailed history of various risk factors and thorough clinical examination, pregnant women were given 75 gm glucose load irrespective of their last meal, on first hospital visit. Venous plasma sample was taken after 2 hours and sent in a sodium fluoride vial. Pregnant women with 2 hours plasma glucose value > 140 mg/dl were diagnosed as GDM according to DIPSI criteria. All of these pregnant women were advised to follow a unrestricted carbohydrate diet and usual activity for three days and come to antenatal clinic after an overnight fasting of 10 - 12 hours. They underwent 2 hour 75 gm OGTT as recommended by WHO guidelines. Blood sample was first collected when patient came fasting and then after 2 hours of 75 gm oral glucose load from an ante cubital vein. GDM was diagnosed if fasting plasma glucose > 126 mg/dl and/or 2 hour plasma glucose value after OGTT to be > 140 mg/dl. All pregnant women were reminded to come for WHO OGTT in fasting state by telephonic call given one day prior to minimise loss of cases.

All the collected data was entered in Microsoft excel spread sheet and analysed using SPSS software. Qualitative data was represented in the form of frequency and percentage while quantitative data was represented using mean and standard deviation. DIPSI criteria was compared with

gold standard WHO criteria and screening parameters like sensitivity, specificity, predictive values, diagnostic accuracy and correlations were calculated. A p value < 0.05 was taken as statistically significant.

Results

The mean age of our study population was 24.95 ± 4.26 years. Maximum number of GDM positive patients were in the age group of 26 - 30 years. The mean BMI of pregnant patients was 22.97 ± 2.15 and majority around 79 % had BMI in the normal range. The mean period of gestation was 26 weeks. Majority of our study population comprised of unskilled workers living in rural areas and thereby were less educated also. Around 67

% of patients were multigravida in our study. Only 5.5 % of patients had family history of GDM or BOH. The p value was statistically significant for association with GDM for major risk factors like advance age, increased BMI, multigravida, less education level, advance gestational age and family history of Diabetes Mellitus or BOH except rural background.

The mean blood sugar by DIPSII criteria was 98.71 ± 29.0 and that by WHO for fasting plasma glucose was 89.16 ± 25.30 and for 2 hour plasma glucose was 106.75 ± 28.48. Table showing correlation between WHO99 & DIPSII is:

Table 1

DIPSII	W		HO		P Value
	Negative		Positive		
	Frequency	Percentage	Frequency	Percentage	
Negative	167	97.7%	8	27.6%	<0.001
Positive	4	2.3%	21	72.4%	
Total	171	100%	29	100%	

The number of GDM cases diagnosed by DIPSII alone were 4, by WHO99 criteria alone were 8 and 21 were diagnosed as having GDM by both criterion. This shows that DIPSII would be able to identify 25/33 (75.75 %) of the patients that would be diagnosed if WHO99 alone criteria would be used. This supports use of DIPSII as a simple, sensitive, effective and feasible test for screening of GDM. Fischer exact test (chi square) is applied to analyze the significance of both tests. P value is extremely statistically significant (p < 0.001) showing that both tests are equally effective and sensitive for the early diagnosis of GDM.

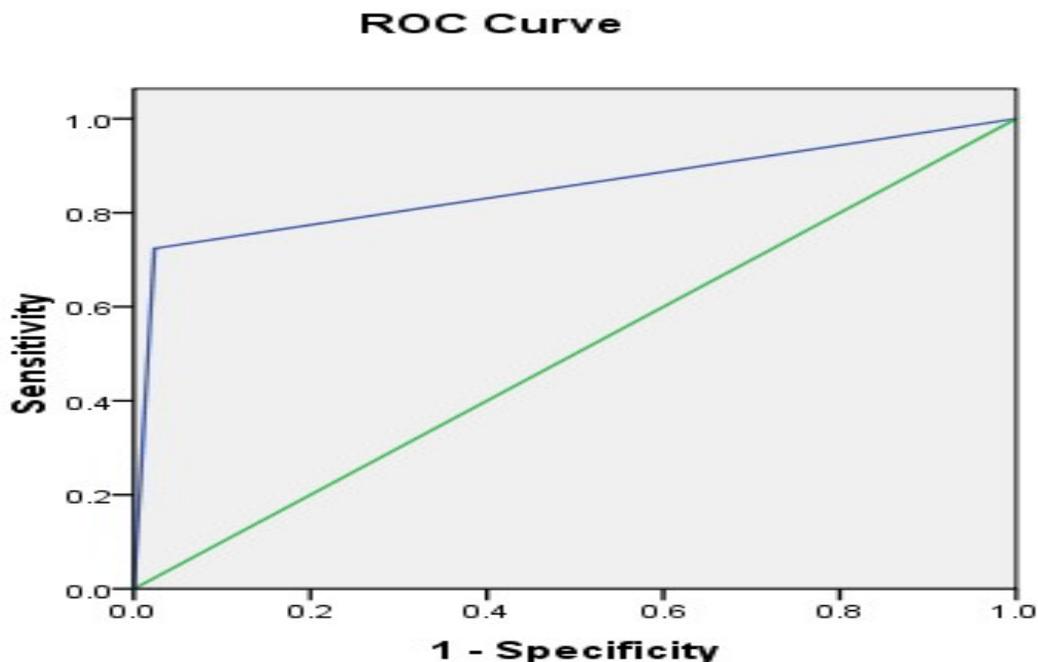
The prevalence of GDM in our study was 12.5 % according to DIPSII criteria and 14.5 % according to WHO99 criteria. Considering the sensitivity and specificity of conventional WHO99 OGTT as 100 %, we have studied the sensitivity of DIPSII to be 72.4 % as that of OGTT and the specificity of DIPSII to be 97.7 % as that of OGTT, which are both comparable. There was no statistically significant difference between 2 hour plasma glucose value of DIPSII & WHO99 criteria (p value < 0.315), showing both values had nearly same diagnostic efficacy for screening of GDM. Table showing various diagnostic parameters of DIPSII are:

Table 2

Sensitivity	72.4%
Specificity	97.7%
PPV	84.0%

NPV	95.4%
Accuracy	94.0%

The ROC curve between WHO OGTT & DIPSI covered an area of 0.850 ($p < 0.05$) with 95 % confidence interval. Pearson's correlation between WHO & DIPSI was 0.746 ($p < 0.001$).



Diagonal segments are produced by ties.

Figure 1

On comparing sensitivity and specificity of different DIPSI glucose values in comparison to WHO OGTT for GDM, value around 97.5 mg/dl showed maximum sensitivity (86.2 %) and specificity (80.1 %).

Discussion

The population of diabetics (including GDM) is expanding exponentially making India the diabetic capital of the world. Various previous studies have showed that treatment of GDM reduced serious maternal and perinatal morbidity and improved woman's health related quality of life [12-14]. Conventional diagnostic criteria like ADA [15] ACOG [16] NICE [17] and IADPSG guidelines [18] are controversial and country specific & do not give any information about perinatal outcome. To standardise diagnosis

of GDM, WHO recommended a 2 hour fasting oral glucose tolerance test. The main drawback of this was that pregnant women was expected to turn up fasting for this test. DIPSI - a modified version of WHO is a one step procedure with a single glyceic value in the antenatal clinic.

This study has supported the increasing prevalence trend of GDM compared to that of 2 % in 1982 [19] and 7.62 % in 1991 [20]. Various confounding factors like race, ethnicity, dietary and cultural differences across India & use of different diagnostic methods used make the use of a single national programme for early diagnosis of GDM complicated. The present study tried to answer this question by comparing sensitivity, specificity and other diagnostic

parameters of DIPSII with WHO99 and found them to be comparable. This data was in consonance with previous studies by

Wahi P *et al* who found sensitivity and specificity of DIPSII as 100 % for diagnosis of GDM; with Sharma *et al* [21] who found sensitivity and specificity of DIPSII as 90.2 % and 97.5 % respectively compared to WHO. Polur *et al* [22] also observed sensitivity and specificity of DIPSII as 82.5 % and 93 % respectively compared to gold standard test.

This study also observed that likelihood of developing GDM increases with the presence of one or more risk factors in the study population. These risk factors were increasing age, multi-parity, lower educational qualifications, increased gestational age, increased BMI and family history of DM or BOH. Our study didn't find statistically significant correlation between residential status and GDM prevalence because of predominantly rural background of our study population, around 62 % thus making data biased and skewed. So the presence of above listed risk factors in pregnant women should alert the treating doctor for more intensive, early and repetitive screening for GDM. This was also in conformity with various previous studies which demonstrated increased prevalence of GDM in high risk population.

In resources limited country like India, where pregnant women rarely come to antenatal clinic in a fasting state and laboratory facilities are either not easily available or accessible, we need to have a single step procedure to diagnose GDM. This study supports the use of DIPSII as a non fasting glucose challenge test which can be used for mass screening since it has equally sensitive diagnostic parameters to conventional used criteria like WHO. So it is a useful and practical test for Indian settings.

Routine universal screening for GDM is paramount to reduce mortality and morbidity

among mothers and the neonates. The results of present study augment the use of DIPSII as a good alternative to conventional and gold standard WHO99 test since it is simple, single, convenient, economical, feasible and serves as both screening and diagnostic test with good diagnostic efficacy. It doesn't require patient to come fasting and multiple pricks can be avoided.

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