

# Predictive Value of Diabetes in Pregnancy Study Group of India Test For Gestational Diabetes Mellitus

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## ABSTRACT

**Objective** To find out the predictive value and accuracy of Diabetes in pregnancy study group of India (DIPSI) test for screening and diagnosis of gestational diabetes mellitus (GDM) taking WHO oral glucose tolerance test (OGTT) 99 criteria as gold standard.

**Study design** Cross sectional study.

**Place & Duration of study** Department of Obstetric & Gynaecology, Dr. Ruth KM Pfau Civil Hospital Karachi, from December 2017 to June 2018.

**Methodology** A total of 351 pregnant women between 24 - 32 weeks of gestation were enrolled for the study. All study participants underwent screening for diabetes mellitus by DIPSI test and WHO OGTT 99 criteria. All received 75-gram glucose load orally irrespective of last meal status and again after three days of unrestricted diet, in fasting state. Glucose level was measured after 2-hour and a value of > 140mg/dL was considered as diagnostic of GDM by both the tests.

**Results** Mean age of women was 29.38±6.8 year, mean gestational age 28.73±3.05 weeks, and mean body mass index (BMI) 25.97±2.80 kg/m<sup>2</sup>. Frequency of GDM was 12.8% and 11.68% by DIPSI and WHO 99 criteria tests respectively. Validity of test showed a sensitivity of 82.9%, specificity 96.5%, positive predictive value (PPV) of 75.6%, and negative predictive value (NPV) of 97.7% with accuracy of 94.8%.

**Conclusion** GDM is commonly reported during pregnancy which can easily be diagnosed with DIPSI test. This is simple, easy to perform, patient friendly test that is reliable and cost effective.

**Key words** Gestational diabetes mellitus, Glucose tolerance test, DIPSI test.

## INTRODUCTION:

International diabetes Federation (IDF) in 2015 reported that the frequency of diabetes mellitus is around 1 in 11 person worldwide. Majority (75%) of them live in low and middle income countries.<sup>1</sup> Diabetes mellitus is commonest medical disorder of

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pregnancy. It complicates 2-5% of pregnancies, of which 90% is contributed by diabetes mellitus occurring during pregnancy called gestational diabetes mellitus (GDM).<sup>2</sup> Incidence of GDM is very high in Indian women as compared to other ethnic groups in south Asia.<sup>3</sup> Pooled prevalence of 10.1% for GDM is observed in south eastern and eastern Asia.<sup>4</sup> Uncontrolled GDM can result in poor maternal and fetal outcome like fetal macrosomia, fetal hypoglycemia and hyperinsulinemia, prematurity, need for cesarean section, and pre eclampsia. For prevention of maternal and fetal complications, it is important to recognize GDM timely through valid screening test.<sup>5</sup> Currently screening of GDM through feasible single step test is under research. However, consensus is necessary to solve this controversy.

Different criteria for GDM diagnosis developed through expert opinion and experiences. All are universally accepted and are in practice. WHO in 1999 introduced simple and feasible one-step screening and diagnostic test for GDM. With WHO 99 criteria, 75-gram glucose in fasting is used. It is a cost effective test.<sup>6</sup> The only drawback is that to assess glucose intolerance in pregnant women main prerequisite is fasting before coming to antenatal clinic or laboratory.<sup>7</sup>

International diabetes federation sponsored a project WINGS (women in India and GDM strategy) in Chennai. WINGS developed a test DIPS I on non fasting women. It was convenient to test for screening and diagnosis of GDM.<sup>8</sup> WINGS program compared DIPS I with WHO 99 criteria taking it as gold standard.<sup>9</sup> The validity of DIPS I is not clear as few studies reported poor sensitivity and specificity.<sup>9,10,11</sup> This study was conducted to assess the usefulness of DIPS I for screening, and diagnosis of GDM taking WHO oral glucose tolerance test (OGTT) 99 criteria as gold standard.

#### METHODOLOGY:

This cross sectional study was conducted at Dr. Ruth KM Pfau Civil Hospital Karachi from December 2017 to June 2018. A total of 351 pregnant women (after sample size calculation) attending antenatal clinic between 24 - 32 weeks of gestation were enrolled for study. Study was approved by institution review board and informed consent was taken from study participants. A non- probability consecutive sampling technique was used.

Women with previous history of gestational diabetes, taking medication that affect glucose metabolism, and those with renal, cardiac, hepatic and respiratory diseases, were excluded from study. A detailed history was taken and general physical and obstetrical examination performed. A standard form was used to record data. All women underwent glucose tolerance test with 75-gram glucose dissolved in glass of water irrespective of last meal and asked to drink in 10 minutes. Subsequent 2-hour venous plasma glucose level measured (DIPS I

criteria). All women had to report after three days with no restriction on type of meal and routine daily life activities. Fasting and subsequent 2-hour glucose load was measured. Diagnosis of GDM was made if 2-hour post glucose plasma sugar was > 140mg/dl by either test.

The continuous variables like maternal age, parity, gestational age, BMI were expressed in mean and standard deviation (Mean±SD). Sensitivity, specificity, positive predictive value, negative predictive value of DIPS I method and diagnostic accuracy were calculated. Categorical variables like family history expressed in frequency and percentage. SPSS version 19 was used for data entry and analysis.

#### RESULTS:

The mean age of the study participants was 29.38±6.8 year. The mean gestational age of the subjects was 28.73±3.05 weeks, and mean BMI 25.97±2.80 kg/m<sup>2</sup>. Out of 351 subjects 45 (12.8%) by DIPS I and 41(11.6%) by WHO 99 criteria had GDM. Seven cases of GDM were false negative by DIPS I test and 11 cases of GDM false positive, as these were not confirmed by WHO 99 criteria.

Sensitivity of the test was 82.9%, specificity 96.5%, PPV 75.6%, NPV 97.7% and accuracy 94.8% (table I). Accuracy of DIPS I with known risk factors of GDM like age, BMI and family history of diabetes was also calculated. Frequency of GDM by DIPS I and WHO 99 criteria in subjects with or without known risk factors of GDM are given in table II and III.

#### DISCUSSION:

Globally GDM is emerging as a major health concern for pregnant women. In Pakistan with low resources and less compliant attitude DIPS I test was used for this study. The International Association of Diabetes Pregnancy Study Group (IADPSG) also accepted and proposed this test for screening of GDM.<sup>12</sup> In our study frequency of GDM was 12.8% and 11.68% by DIPS I and WHO 99 respectively. The frequency of GDM is almost comparable with other studies.<sup>11</sup>

**Table I: Comparison of Results of DIPS I and OGTT**

Statistical Parameter I	Frequency	Statistical Parameter II	Ratios	Estimates
True Positive	34	Sensitivity	34/41	82.9%
False Positive	11	Specificity	299/310	96.5%
False Negative	07	PPV	34/45	75.6%
True Negative	299	NPV	299/306	97.7%
		Accuracy	34+299/351	94.8 %

**Table II: Frequency of GDM With or Without Known Risks Factors By DIPSI and WHO OGTT 99 Criteria**

Age (year)	DIPSI	%	WHO OGTT	%
< 30	23/201	11.44	20/201	9.9
>30	22/150	14.6	21/150	14.0
<b>BMI (Kg/m<sup>2</sup>)</b>				
<25	22/126	17.4	21/126	16.6
>25	23/225	10.2	20/225	8.8
<b>Family History</b>				
Yes	11/67	16.4	10/67	14.9
No	34/284	11.9	31/284	10.9

**Table III: Validity of DIPSI Versus Gold Standard WHO OGTT 99 With And Without Known Risk Factors**

			Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
<b>Age (year)</b>							
<b>&lt;30</b>	TP=19 FN=1	FP=4 TN=177	95	97.9	82.6	99.4	97.5
<b>&gt;30</b>	TP=15 FN=6	FP=7 TN=122	71	94.6	68.2	95.3	91.3
<b>BMI kg/m<sup>2</sup></b>							
<b>&lt;25</b>	TP=18 FN=3	FP=4 TN=101	85.7	96.2	81.8	97.1	94.4
<b>25-29</b>	TP=11 FN=2	FP=6 TN=167	84.6	96.5	64.7	98.8	95.7
<b>&gt;30</b>	TP=5 FN=2	FP=1 TN=31	71.4	96.9	83.3	93.9	93.2
<b>Family History</b>							
<b>Yes</b>	TP=8 FN=2	FP=3 TN=54	80	94.7	72.7	96.4	92.5
<b>No</b>	TP=26 FN=5	FP=8 TN=245	83.9	96.8	76.5	98	95.4

In a study from Pakistan with DIPSI criteria the frequency of GDM was reported as 7.6%.<sup>13</sup> Frequency of this medical disorder of pregnancy is 13.4 % as reported in one study.<sup>14</sup> Screening test to identify women with GDM is therefore important. In this study DIPSI test had an accuracy of 94.8% which is similar to another report where it was 98.25%.<sup>15</sup>

DIPSI was found useful as screening and diagnostic test.<sup>6</sup> A test with good sensitivity and PPV is associated with low false negative results. The test that overestimates may lead to psychological stress, unnecessary treatment, wastage of resources and impair quality of life. DIPSI criteria is criticized in a study. It is argued that if test is done in the fasting state there is risk of missing significant number of GDM cases and recommend that fasting plasma glucose should be part of making a diagnosis.<sup>16</sup>

American Diabetic Association (ADA) recommended

selective screening (screening with GDM risk factors) instead of universal screening (irrespective of GDM risk factors).<sup>17</sup> Known risk factors of GDM are advancing age of > 25 years, BMI > 25 Kg/m<sup>2</sup> and family predisposition.<sup>18</sup> We compared the frequency of GDM with or without risk factors by both criteria. In western countries age is the most important risk factor for GDM.<sup>5</sup> Mean age of GDM was 29.38±6.8 year in our study. One of the reasons of high frequency in relatively younger population is trends of early marriages in India as reported in one study.<sup>5</sup> We found that age less than 30 years is not free of risk for GDM.

High BMI is a well-known risk factor for GDM.<sup>11</sup> In this study mean BMI was 25.97±2.80 kg/m<sup>2</sup> and frequency of GDM in cases < 25kg/m<sup>2</sup> was 10.2% and 8.8% by DIPSI and WHO 99 criteria. GDM is very high among those having GDM in their families. The family history of diabetes mellitus increases the susceptibility to GDM as high as nine times

compared to control group with no family history.<sup>19</sup> For population belonging to ethnic group with high prevalence of diabetes mellitus universal screening is a better option.<sup>20</sup> Currently, for South and Southern Asian descent group, recommendation is universal. Screening of GDM irrespective of risk factors results in good glycemic control and, helps to control both the maternal and fetal complications. Our study also favors screening of all pregnant women irrespective of risk factors in our population as cases without risk factors are not free of developing GDM. New concept is early universal screening of GDM which means screening of pregnant women soon after the diagnosis of pregnancy irrespective of risk factors.<sup>21</sup> Repeat screening is recommended at 24-32 weeks for those not found to have GDM in early screening. We opted to screen once between 24-32 weeks according to the recommendation and found it cost effective. The limitation of this study includes from a single center and small sample size. A larger multicenter study is therefore suggested for getting a more reliable population based data. Fetomaternal outcome was also not analyzed in this study.

#### CONCLUSION:

Random one step DIPSI test is simple, feasible and economical test for screening of GDM. Screening between 24-32 weeks of gestation was ideal time for conducting this test.

#### DISCLOSURE:

This is dissertation based study.

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