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COMPARISON OF SINGLE-STEP VERSUS TWO-STEP TEST FOR SCREENING AND DIAGNOSIS OF GDM AND FETO-MATERNAL OUTCOME

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ABSTRACT

OBJECTIVE To evaluate the effectiveness and predictive value of single step Diabetes in Pregnancy Study Group India (DIPSI) test in comparison to two step 100gram oral glucose tolerance test (OGTT) for screening and diagnosis of *Gestational Diabetes Mellitus* (GDM).

METHODS Total 245 singleton pregnant women between gestation age 24 to 28 weeks attended antenatal clinic of RGGWCH, Puducherry were included for this prospective comparative study. They were divided into low and high risk groups. All women included in the study underwent DIPSI test followed by 100gmOGTT after one week irrespective of DIPSI test result. They were followed throughout pregnancy till delivery and perinatal outcomes were noted.

RESULT- The prevalence of GDM in low and high risk group was 4.08%(CI:1.12 10.12) and 10.20%(CI:5.46 14.17) respectively.The overall prevalence was 7.76%(CI:4.73 11.85). Age >25years, BMI >25, PCOS and high and middle socioeconomic status had significant correlation with occurrence of GDM. In comparison to 100gm-OGTT, DIPSI test had sensitivity of 100%(CI:82.35 100), Specificity-92.04%(CI:87.70 95.21), PPV-51.35%(CI:34.40 68.08), NPV-100%(CI:98.24 100), PLR-12.56(CI:8.06 19.56), NLR-zero and Area under ROC curve (AUC) -0.96(CI:0.93 0.98) in our study. DIPSI test had not only picked up those entire tested positive for GDM by 100gm OGTT, but also proved sensitive enough to pick up twice as more GDM cases in ethnic Indian women, who have high prevalence of diabetes. There were favourable feto-maternal outcomes, in terms of mode of delivery, birth weight and neonatal complications.

CONCLUSION Single step DIPSI test was found to be inexpensive, simple, feasible, patient friendly does not require fasting state and reliable method for universal screening of pregnant women in developing countries like India.

KEYWORDS : DIPSI, GDM, OGTT, Risk factors

INTRODUCTION:

GDM is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. If left undetected or uncontrolled, GDM is a formidable threat to the health of the mother and her unborn child. Women with GDM are seven times more likely to develop Type–2 diabetes in later life compared to women who have not had GDM. As a result of the global trend of increased maternal obesity, it is estimated that approximately-15% of all pregnant women worldwide develop GDM (1).

The diagnosis and management of GDM is a trans-generational preventive medicine, full of potential to avert this non-communicable disease in a whole new generation, if it starts before birth. So, early screening and diagnosis of GDM in pregnant women is very important. The prevalence of diabetes is increasing globally and nowadays India is being recognized as the diabetic capital of the world. Thus, it is an important public health issue. Hence, universal screening during pregnancy has become important in India. For this, we need a simple test which is cost effective and feasible. DIPSI is a single step diagnostic test and it can be performed in the fasting or non-fasting state irrespective of the last meal timing (2,3,4). The aim of this study is to compare the diagnostic accuracy of DIPSI with gold standard 100gmOGTT for detection of GDM.

MATERIAL AND METHOD:

This prospective comparative study was conducted in RGGWCH, Puducherry from March 2013–February 2014 after approval by institutional scientific and ethical committee. The minimum reckoned sample size was 92 (in each group) by using OpenEpi software version-3.01, with prevalence of GDM in India-13.9%; the power of study-80% and with the consideration of the difference between the study groups being significant at 'p'-value<0.05.

In this study 425 cases were initially enrolled, but only 245 cases could be included, because 170 cases didn't turn up in follow-up for 100gmOGTT in fasting state. Thus, 245 healthy singleton pregnant women between 24 to 28 weeks gestation were included in the study. They were divided into low and high risk groups as follows.

INCLUSION CRITERIA:

Low Risk Group: Ethnic Indian women with no risk factors:–98(40%) cases.

***High Risk Group*:** Ethnic Indian women with one or more risk factors as described below:–147(60%) cases.

1. Age>25 years
2. Body mass index (BMI) >25
3. Previous history of GDM
4. Previous history of delivery of big baby >3.5 kg
5. Positive history of recurrent pregnancy loss (RPL)
6. Positive history of still born/ Intra Uterine Death (IUD)/congenital malformation (CMF)
7. Positive history of Poly Cystic Ovarian Syndrome (PCOS)
8. Positive history of Diabetes Mellitus (DM) in first degree relative

EXCLUSION CRITERIA:

(1) Known case of Type-1/2DM
(2) Medical/Surgical complications eg. Anaemia, Cardiac disease, Chronic hypertension, Renal disease etc.
(3) Multiple pregnancy
(4) Patients not consenting to the study

***REAGENT*:** Glucose oxidase-peroxidase (GOD-POD) method was used.

After informed written consent, detailed history, general and obstetrical examination, the women fulfilling inclusion criteria categorized into low and high risk groups. All women in both groups were administered DIPSI test (modified WHO procedure: 2-hours 75gm-OGTT single value) irrespective of the time of last meal, plasma glucose (PG) is collected after 2-hours. GDM is diagnosed if 2hours-PG is ≥140mg/dl (7.8mmol/l) (2,3,4).

After one week of DIPSI test, all women were further subjected to 100gm-OGTT (gold standard:3 hours-4 values) after atleast 8-hours of fasting and they were evaluated on basis of Carpenter and Coustan criteria as follows (3,4,5).

Fasting plasma glucose (FPG) ≥95mg/dl

1-hour PG	≥180mg/dl
2-hours PG	≥155mg/dl
3-hours PG	≥140mg/dl

- If any 2 or more values ≥ above values, then the case was labelled as GDM
- If only one value ≥ above values, then the case was labelled as impaired glucose tolerance (IGT).

All antenatal women diagnosed GDM by DIPSI and 100gmOGTT were evaluated and managed by diet control and insulin if required. We have managed GDM cases on basis of DIPSI test results by diet control for 2-weeks; then retested. If FPG>90mg/dl (>5.0mmol/l) and postprandial PG>120mg/dl (>6.7mmol/l), then patient was admitted and evaluated; if needed insulin administered in addition to diet control.

All women were followed throughout pregnancy till delivery and mode of delivery was noted. All babies were examined after birth, their APGAR score, birth weight and congenital anomaly was recorded and they were screened for hypoglycaemia. Birth weight >3.5 kg was considered as macrosomia.

Statistical Analysis: All data were entered on Microsoft excel sheet analyzed using SPSS version-20. Non-parametric (Chi-square) test was used to test the difference between two groups. A 'p'-value <0.05 was considered as statistically significant and 'p'-value <0.01 highly significant. Sensitivity, specificity, predictive values and likelihood ratios were calculated using MedCalc version-12.7.8.

***RESULTS*- TABLE - 1: Demographic and obstetric characteristics**

Group→ Characteristic ↓		Low risk group(N=98)		High risk group(N=147)		'p'-value DIPSI test
		N (%)	GDM (%)	N (%)	GDM (%)	
Socioeconomic status	**Low**	83(84.69%)	1(1.20%)	123(83.67%)	19(15.45%)	0.0001
	Middle	12 (12.24%)	3(25%)	19 (12.93%)	8(42.11%)	
	High	3(3.06%)	3 (100%)	5(3.40%)	3(60%)	
Gravidity	**Primigravida**	63(64.29%)	5(7.94%)	56(38.09%)	14(25%)	0.75
	Multigravida	35(35.71%)	2(5.71%)	91(61.90%)	16(17.58%)	
Mode of delivery	**Vaginal delivery**	78(79.59%)	7(8.97%)	80(54.42%)	13(16.25%)	0.21
	LSCS	20(20.41%)	0	67(45.58%)	17(25.37%)	
Birth weight	**Low birth weight (≤2.5kg)**	9(9.18%)	1(11.11%)	13(8.84%)	1(7.69%)	0.167
	Normal (2.6-3.5kg)	82(83.67%)	6(7.32%)	115(78.23%)	24(20.87%)	
	Macrosomia (>3.5kg)	7(7.14%)	0	19(12.93%)	5(26.32%)	

Most of the cases were from low socioeconomic status in both groups, but GDM was found more in middle and high socioeconomic status, which was statistically highly significant. Majority of the cases were primigravida in low risk whereas multigravida in high risk group. Most of cases in both groups had vaginal delivery and normal birth weight of baby. There was no statistical significant correlation of GDM with gravidity, mode of delivery and birth weight (Table-1).

TABLE-2: Fetal outcome

Neonatal outcome		Low risk group(N=98)		High risk group(N=147)	
		N (%)	GDM (%)	N (%)	GDM (%)
APGAR Score	**8/10(Normal)**	98(100%)	7(7.14%)	140(95.24%)	29(20.71%)
	< 8/10	0	0	4(2.72%)	0
	IUD	0	0	3(2.04%)	1(33.33%)
Neonatal complications	**Neonatal jaundice**	18(18.37%)	2(11.11%)	22(14.97%)	6(27.27%)
	CMF	1(1.02%)	0	1(0.68%)	0
	Respiratory distress	0	0	4(2.72%)	0
	IUD	0	0	3(2.04%)	1(33.33%)
	Hypoglycemia	0	0	0	0
	Nil	79(80.61%)	5(6.33%)	117(79.59%)	23(19.66%)

In low risk, all had normal APGAR score, while in high risk group, 140 babies had normal APGAR score, 4 babies had APGAR score < 8/10 and 3 babies suffered IUD. In both groups, most of the babies had no complications. Stillbirth occurred in one GDM case, 8 GDM cases had neonatal jaundice and no neonatal hypoglycemia case was detected in both groups (Table-2).

Table -3: Risk factors in high risk group (N=147 cases)

Sl. No.	Risk Factors	N (%)	GDM: DIPSI test (%)	'p'-value
1	Age>25 years	100(68.03%)	23(23%)	0.015
2	BMI >25	60(40.82%)	17(28.33%)	0.0001
3	Family history of DM(First degree relative)	60(40.82%)	14(23.33%)	0.066
4	Previous history of unexplained still birth/IUD/CMF	16(10.88%)	1(6.25%)	0.508
5	History of delivery of big baby(>3.5kg)	5(3.40%)	1(20%)	0.748
6	History of RPL	3(2.04%)	1(33.33%)	0.939
7	History of PCOS	2(1.36%)	2(100%)	0.018
8	Previous history of GDM	1(0.68%)	1(100%)	0.329

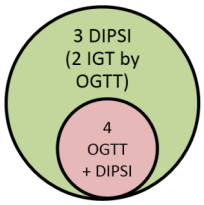
In 30 GDM cases detected by DIPSI test in high risk group, 9 women had single risk and 21 had multiple risk factors. Age>25years, BMI>25 and history of PCOS had significant correlation with occurrence of GDM (Table-3).

TABLE- 4: GDM detected by DIPSI and 100gm-OGTT

TEST	Low risk group (N=98)	High risk group(N=147)	'p'-value (difference between Low and High risk)	Total (N=245)
	GDM (%)	GDM (%)		GDM (%)
DIPSI	7(7.14%)	30(20.41%)	0.008	37(15.1%)
100gm-OGTT	4(4.08%)	15(10.2%)	0.131	19(7.76%)
'p'-value*	0.535	0.023		0.016

* Difference between DIPSI and 100gmOGTT

The overall GDM occurrence by DIPSI was 15.1 %(37/245); while it was 7.76 %(19/245) by 100gm-OGTT. The difference in number of GDM cases by DIPSI (37) and 100gmOGTT (19) was found statistically significant (p-0.016) (Table-4). 19 GDM cases detected by 100gmOGTT were also having positive DIPSI test. Thus, 18 DIPSI positive cases were not detected GDM by 100gmOGTT; 3 cases were in low and 15 cases in high risk group. 2 out of 3 cases in low and 4 out of 15 cases in high risk groups were detected as IGT by 100gm-OGTT. One case in low and 11 cases in high risk group were not detected either as GDM and IGT by100gm-OGTT (Fig.1).



Low risk group

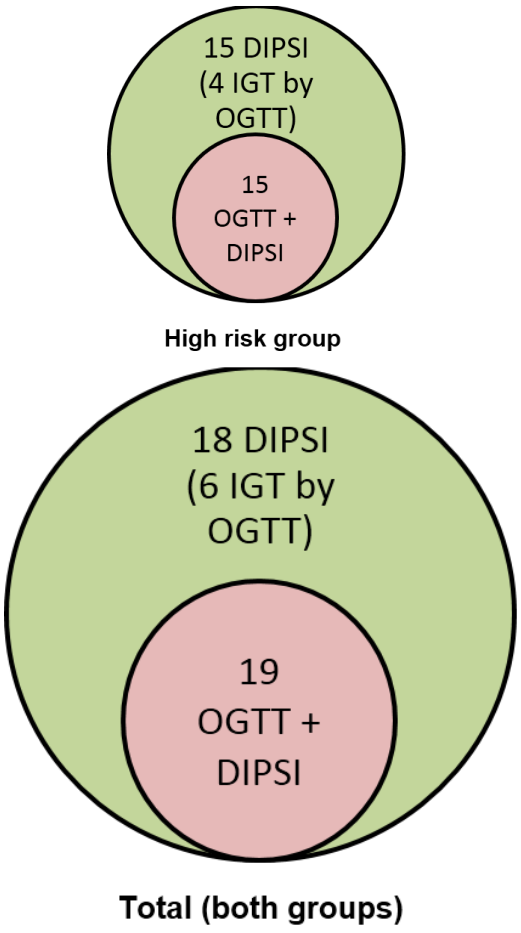


Fig. 1 Details of GDM cases by both tests

In low risk, there is no statistical significant difference (p-0.535) between DIPSI and 100gmOGTT findings but in high risk group, the difference in the detection of GDM by two methods is statistically significant (p–0.023). There is no statistically significant difference (p-0.131) in GDM occurrence between low and high risk, when diagnosed by 100gmOGTT, while there is statistically highly significant difference (p-0.008) between the two groups by DIPSI test (Table-4).

The average PG value for 37 GDM cases detected by DIPSI test was 165mg/dl (range: 140-243). It was 153 mg/dl (range: 140-172) in low risk and 168 mg/dl (range: 140-243) in high risk group.

Out of 37 GDM cases, 13 cases were managed on both diet control and insulin while 24 cases were managed on diet control alone. Amongst these 13 insulin treated cases, 2 were from low and 11 were high risk group.

TABLE - 5: Statistical profile of DIPSI test in comparison to 100gm-OGTT

Statistical criteria	Low risk group(N=98)	High risk group(N=147)	Overall(N=245)
Sensitivity	100%(CI*:39.76100)	100%(CI:78.20100)	100%(CI:82.35100)
Specificity	96.81%(CI:90.9699.34)	88.64%(CI:81.9593.50)	92.04%(CI:87.7095.21)
Prevalence	4.08%(CI:1.1210.12)	10.20%(CI:5.4614.17)	7.76%(CI:4.7311.85)
Positive Likelihood Ratio(PLR)	31.33(CI:10.2995.40)	8.80(CI:5.4614.17)	12.56(CI:8.0619.56)
Negative Likelihood Ratio(NLR)	0.00	0.00	0.00
Positive Predictive Value(PPV)	57.14%(CI:18.4190.10)	50%(CI:31.3068.70)	51.35%(CI:34.4068.08)
Negative Predictive Value(NPV)	100%(CI:96.03100)	100%(96.90100)	100%(CI:98.24100)
Area under the ROC Curve(AUC)	0.98(CI:0.941.00)	0.94(CI:0.890.97)	0.96(CI:0.930.98)

*CI-95%Confidence Interval

In the low risk group with sensitivity-100%(CI: 39.76 100), specificity-96.81%(CI: 90.96 99.34) with disease prevalence-4.08%(CI: 1.12 10.12) and with PLR-31.33(CI: 10.29 95.40) and NLR-zero, PPV-57.14% (CI: 18.41 90.10), NPV-100%(CI: 96.03 100)and area under the ROC curve (AUC) - 0.98(CI:0.94 1.00) reflect that DIPSI scores as an excellent screening test (Table-5).

In the high risk group with sensitivity-100%(CI:78.20 100), specificity-88.64%(CI:81.95 93.50) with disease prevalence-10.20%(CI:5.46 14.17) and with PLR-8.80(CI:5.46 14.17) and NLR-zero, PPV-50%(CI:31.30 68.70), NPV-100%(96.90 100) and AUC-0.94(CI:0.89 0.97) show that DIPSI is again an excellent screening test (Table-5).

The overall, sensitivity-100%(CI:82.35 100), specificity-92.04%(CI:87.70 95.21) with disease prevalence-7.76% (CI:4.73 11.85) and with PLR-12.56(CI:8.06 19.56) and NLR-zero, PPV-51.35%(CI:34.40 68.08), NPV-100%(CI:98.24 100) and AUC-0.96(CI:0.93 0.98). Hence, DIPSI has excellent capacity to rule out GDM and scores well not only as a screening but also as a diagnostic test statistically (Table-5).

DISCUSSION- In this study, the overall prevalence of GDM by DIPSI is 7.76%; prevalence is more in high risk (10.2%) in comparison to low risk group (4.08%). Though GDM prevalence is more in high risk, it is not absent in low risk group. This signifies the need of universal screening for GDM in pregnant women in India. Abu-Heija et al (6) also recommends universal screening in the Omanian population. They found GDM prevalence was 7.49% (10.07% in high and 5.35% in low risk groups). Mishra S (7) mentioned about the availability of different screening and diagnostic procedures even in same country and among different countries. She also recommended universal screening for GDM in ethnic Indian population, who are at higher risk of developing GDM and subsequent Type-2 diabetes. But there is an ambiguity on the screening procedure to be adopted.

We have found significant correlation of age>25 years with GDM occurrence. Abha and Avinashi (8) also found significant correlation with age>25 years. We found increased GDM occurrence in cases with BMI>25 which was statistically highly significant. This proved that obesity is significant risk factor for GDM and it is also supported by several studies by Kalra et al (9), Nielson et al (10), and Nilofer et al (11). This may be due to increased demands on maternal metabolism during pregnancy from excess weight, resulting in imbalances in hormonal carbohydrate regulation mechanisms and insulin sensitivity.

In our study, no significant correlation was found between family history of DM, this was similar with the study done by Bhatt et al (12). However, Seshiah et al (13) had found that there was a significant association of GDM with family history of DM.

History of bad obstetric history was present in only 23(15.65%) cases and there was no statistical correlation. PCOS was found in 2(1.36%) cases having significant correlation. Hai-Feng Yu et al (14) conducted a PRISMA-compliant systematic review and meta-analysis in China and found that PCOS in pregnancy was associated with greater risk of GDM.

Socioeconomic status was found to be highly significant in our study; GDM was found more common in middle and high socioeconomic status. This is similar as reported by Rajput et al (15) who conducted their study in a tertiary care hospital in Haryana, India while it is in striking contrast with the study in an Atlantic population by Cullinan et

al (16). They found high incidence in low socioeconomic group.
In our study GDM was detected more in primigravida, however there was no significant correlation with gravidity. This is in contrast with the study by Sharma et al (17) conducted in Jammu who stated that prevalence of GDM increased with gravidity.

There was no statistical significant correlation with mode of delivery and birth weight as is expected with prompt and alert management of GDM. Veerasamy et al (18) also observed that diagnosing GDM with a cut off of 2-hours PG>140mg/dl and treating women with positive diagnosis is worthwhile, because of decreased macrosomia rate, fewer emergency Cesarean sections and serious perinatal morbidity.

More GDM cases were diagnosed by DIPSI because the threshold value of DIPSI is much lower (≥ 140mg/dl) than the 100gm-OGTT. DIPSI identifying a large number of cases may have a greater potential for prevention in ethnic Indian women, who have high prevalence of diabetes. There were favourable feto-maternal outcomes, in terms of mode of delivery, birth weight and neonatal complications and lower occurrence of stillbirth.

In comparison to 100gmOGTT, DIPSI has sensitivity-100% (CI: 82. 35 100), Specificity-92.04%(CI:87.70 95.21), PPV-51.35% (CI:34. 40 68.08), NPV-100%(CI:98.24 100), PLR-12.56 (CI:8.06 19.56), NLR-zero and AUC-0.96(CI:0.93 0.98) which signifies the role of DIPSI as a single step test for screening as well as diagnostic purpose in Indian setup. Sharma et al (19) conducted a study in North India and compared DIPSI with 75gm-WHO-OGTT. They found that DIPSI had sensitivity of 90.2%(CI:78.6 96.7), specificity-97.5% (CI:95.8 98.7), PPV-77.97% (CI:65.27 87.70), NPV-99.03%(CI: 97.76 99.68), PLR-36.43(CI:21.13 62.78), NLR-0.10(CI:0.04 0.23) and AUC-0.97(CI:0.95 0.98). Hence, it is prudent to say that the DIPSI scores well statistically not only as a screening but also as a diagnostic test. The expected greater patient compliance for this test as well as the necessity of universal testing of antenatal patients enhances the importance of DIPSI test. It is difficult for pregnant women to report for glucose challenge test in a fasting state as shown in our study, 170 cases didn't report for follow-up 100gm-OGTT in fasting state and thus lesser number cases were included for this study.

CONCLUSION:

Single step DIPSI is a reliable, inexpensive and simple test; irrespective of fasting state for diagnosis of GDM especially in an overpopulated country like India with shortage of resources and lab facilities. Taking multiple venous samples requires extra cost, manpower, resources and also not feasible as many pregnant women may be lost to follow-up in fasting state. DIPSI test avoids multiple visits, multiple pricks and analysis of multiple samples. More GDM cases can be diagnosed when universal rather than risk related screening is applied.

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