Original Research Article

The validity of single step test (DIPSI) for screening for GDM in all trimesters of pregnancy

Gayam S[1], Madhurima P[2], Paul S[3], Tallavajhula M[4]

[1]Dr. Susheela Gayam, DGO HOD, [2]Dr Paaka Madhurima DGO, [3]Dr Sashikala Paul, [4] Dr Mythili Tallavajhula, All are affiliated with Department of Obstetrics and Gynaecology, Vijay Marie Hospital & Educational Society, Khairatabad, Hyderabad, Telangana, India

Address for correspondence: Dr. Susheela Gayam, Email: sushgayam@yahoo.com

Abstract

Purpose: To evaluate the validity of DIPSI, (Diabetes and Pregnancy Study Group India) a single step test, as a screening tool for GDM and to find out the incidence and onset of GDM with respect to period of gestation. **Materials and Methods:** One year prospective study was conducted on 300 antenatal women in all three trimesters with DIPSI – Single step test. DIPSI positive patients underwent diagnostic OGTT, by 75 gm glucose. Patients were diagnosed as GDM by WHO Criteria (1999). **Results:** DIPSI had sensitivity of 100%, specificity of 94.6%. Of the 300 patients subjected to the study, overall incidence of GDM was 25.3% and 0.7% were diagnosed with overt diabetes. During the first trimester 4% had GDM whereas 0.7% had overt diabetes. During the second and third trimester 12.5% and 15.3 % of patients were newly diagnosed with GDM respectively. **Conclusion:** This evidence not only validates DIPSI as simple and efficient screening test but also emphasizes the importance of subjecting all the pregnant women in all 3 trimesters to test for screening for GDM. And therefore this test should become part of the routine antenatal investigations.

Key words: Gestational Diabetes Mellitus, DIPSI - (Diabetes in pregnancy study group in India), Oral glucose tolerance test.

Introduction

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance with onset or recognition during pregnancy. Women with GDM are at increased risk of future diabetes predominantly type 2 diabetes mellitus (DM) and is also associated with increased risk of fetal morbidity and mortality. The prevalence of GDM in India varies from 3.8 to 21% in different parts of the country, depending on geographical locations and diagnostic methods used [1-3]. GDM affects up to 15% of pregnant women worldwide, India alone has an estimated 4 million women with GDM.

Pregnancy is considered to be a diabetogenic state characterized by exaggerated rate and amount of insulin release, associated with decreased sensitivity to insulin at cellular levels. Hormones like estrogen, progesterone, human placental lactogen, cortisol and growth hormone are anti insulinogenic. These hormones increase in mid pregnancy period and cause abnormal glucose tolerance in some women rendering them prone for gestational diabetes.

There are lot of controversies regarding many aspects of GDM. Important being type of screening, whether universal or selective, which screening test and diagnostic test to follow, about ideal cut off levels, whether to treat or not, how to treat best so on and so forth. Unfortunately there is no universally accepted gold standard for diagnosis of GDM and the commonly utilized methods and threshold criteria for diagnosis of GDM in themselves give different results. In the usual screening protocol recommended by ADA, which is universally followed, all pregnant patients are screened with 50gm GCT. If the patient is test screen positive GCT >140mg/dl the patient is asked to come back for 3hr 100gm GTT.

According to study done by Seshaiah et al 23% of screen positive women do not return for the confirmatory 3 hr. OGTT [4]. This phenomenon of no show occurs because the women have to come to antenatal clinic on two occasions for the blood test by

Manuscript Received: 14th Feb 2016
Reviewed: 26th Feb 2016
Author Corrected: 20th March 2016
Accepted for Publication: 31st March 2016

this two step protocol. Also the requirement of a number of blood samples for the diagnosis of GDM is not feasible and conducive especially in the Indian context. Hence for Universal screening, Seshaiah et al suggested a single step 75gm GCT (DIPSI-Diabetes In Pregnancy Study Group India) instead of two step procedure. This method serves as both one step screening and diagnostic procedure and is easy to perform besides being economical [5].

Insulin is detectable in fetal pancreas as early as nine weeks after Conception. An increase in beta cell mass and insulin secretion in the fetus occurs by the 16th week of gestation, in response to maternal hyperglycemia. The priming of the fetal beta cells may account for the persistence of fetal hyper insulinaemia throughout pregnancy and risk of accelerated fetal growth even when the mother enjoys good metabolic control in later pregnancy. This necessitates performing the test procedures to diagnose GDM in the first trimester itself. Further, early detection and care, results in a better fetal outcome.

There are only a few studies done on screening for GDM in all three trimesters of pregnancy in India, therefore the following study is undertaken to screen for GDM in pregnancy in all trimesters in the pregnant women attending antenatal clinic in Vijay Marie Hospital & Educational Society using single step procedure (DIPSI). This study also helps to determine the incidence of GDM with respect to different period of gestation. This study screens for GDM in all three trimesters of pregnancy thus helps to find, missed out cases in 1st and 3rd trimester if usual screening test done at 24-28wks. By using a single step method in the first trimester itself we will be able to pick up the cases who have pre gestational as well as early onset gestational diabetes mellitus. The test also is less time consuming and convenient for the patient.

Materials and Methods

One year descriptive/prospective study done from June 2014 to June 2015 on 300 pregnant women who were registered in 1st trimester for antenatal checkup at Vijay Marie Hospital from June –September 2014, they were followed up to 9 months. All pregnant women in 1st trimester, irrespective of maternal age and gravidity, presence or absence of clinical or historic risk factors of GDM are included in the study. Known diabetic patients before pregnancy (pre gestational Diabetes) were excluded. The selected patients were briefed about the nature of the study, details of the test and a written informed consent was obtained. Demographic data like age and obstetric history along with relevant history was recorded on predesigned and pretested proforma. A detailed history is taken, general physical examination including BMI, systemic examination and obstetric examination was done. Body Mass Index was calculated based on formula - BMI = weight (kg)/Height (m2). BMI in the range of <18.5kg/m2 were considered as underweight,18.5-24.9kg/m2 were considered as normal, 25-29.9kg/m2 were considered as overweight, >30kg/m2 were considered as Obese.

The Pregnant women in first trimester who were selected in the study were given 75 grams of glucose dissolved in 300 ml of water and asked to drink it over a five minute period, irrespective of time of the day and her last meal. After 2 hours of ingestion of glucose, venous blood is drawn. The plasma glucose is estimated by glucose oxidation and per oxidation (GOD-POD) method. If plasma glucose value is ≥ 140mg/dl, the screening is considered as positive. If test results are negative they undergo a repeat test at 24-28wks and if found negative test is repeated at 32-34wks gestational age. Patients with glucose value of 200mg/dl or more are directly diagnosed as GDM without the need for OGTT. The DIPSI positive patients underwent a diagnostic OGTT, by 75gm of glucose. Three days prior to OGTT test, patients are asked to take normal unrestricted diet. After overnight fasting of 8-14 hours, a fasting blood sample was drawn; following which 75gm of glucose dissolved in 300-400ml water is given orally. Thereafter venous glucose plasma levels are assessed after 2hours. Patients were diagnosed as GDM by WHO Criteria (1999) [FBS >126mg/dl, post 75gm glucose load 2hr PG >140mg/dl. Any one value must be positive.]

Results

After collecting data, statistical analysis was done by using Descriptive statistics – Mean, Standard deviation, and the inferential statistics - chi square test and SPSS 17th version of software. In the present study, majority (48.7%) had age between 20 to 24 years followed by 25 to 29 years (31.7%), 30 to34 years (9.3%), 15 to 19 years (9%) and 35-40 years (1.3%). Over all Mean Age was 24.07 ± 3.77 years, Range being 17-35years. 157 (52.3%) women had BMI in the range

of 25-29.9 Kg/m2, followed by 117 (39%) in range of 18.5-24.9 kg/m2 and 26 (8.7%) women >30kg/m2. Overall Mean BMI was 25.5 ± 2.74 kg/m2 with range being 20-32 kg/m2.

According to DIPSI incidence of GDM in 1st trimester is 4.6% and overt diabetes is 0.7%. During the 2nd trimester 23 patients lost to follow up and 16 patients were screened as GDM positive during 1st trimester. Of the remaining 261, 39(14.9%) patients were newly screened as GDM positive. During the 3rd trimester, 27 more patients lost to follow up. 16 patients were screened as GDM positive in 1st trimester and 39 patients were screened as GDM positive during second trimester. Of the remaining 195 patients, 35 (17.9%) patients were newly screened as GDM positive. According to WHO (1999) criteria in present study, 12(4%) were diagnosed to have GDM in 1st trimester, 2(0.7%) to have overt diabetes. In 2nd trimester 23 lost follow up, out of remaining 263 women, 33 (12.5%) were newly diagnosed to have GDM, in 3rd trimester 27 lost for follow up 31(15.3%) were newly diagnosed as GDM.

Table-1: Comparison of incidence of GDM according to DIPSI & WHO (1999) criteria

	1st Trimester		2nd Trimester		3rd Trimester	
	DIPSI	**WHO(1999)**	**DIPSI**	**WHO(1999)**	**DIPSI**	**WHO(1999)**
Normal	94.7% (284)	95.3% (286)	85.1% (222)	87.5% (230)	82.1%(160)	84.7% (172)
GDM	4.6% (14)	4% (12)	14.9% (39)	12.5% (33)	17.9%(35)	15.3% (31)
Overt Diabetes	0.7% (2)	0.7% (2)	0%	0%	0%	0%
Total	100% (300)	100%(300)	100%(261)	100% (263)	100%(195)	100% (203)

Table-2: Distribution of cases according to DIPSI and WHO

WHO

	Positive	**Negative**	**Total**
Positive	78 (a)	12(b)	90
Negative	0(c)	210(d)	210
Total	78	222	300

DIPSI

1. Sensitivity = a/a+c x 100 = 100%
2. Specificity = d/b+d x 100 = 94.6%
3. Positive predictive value = a/a+b x 100 = 86.7%
4. Negative predictive value = d/c+d x 100 = 100%

Table-3: Association of Age with GDM in all three trimesters.

Age (years)	1st Trimester		2nd Trimester		3rd Trimester	
	GDM Pts	**Percentage**	**GDM Pts**	**Percentage**	**GDM Pts**	**Percentage**
15-19	0	0%	4	12.12%	1	3.2%
20-24	6	42.9%	14	42.42%	12	38.7%
25-29	7	50%	11	33.33%	15	48.4%
30-34	1	7.1%	4	12.12%	3	9.7%
35-40	0	0%	0	0%	0	0%
Total	14	100%	33	100%	31	100%
P value	>0.05		>0.05		>0.05	

There was no positive correlation with increasing AGE and increase in incidence of GDM in all three trimesters P value > 0.05.

Table 4: Association of BMI with GDM in all three trimesters

BMI (kg/m2)	1st Trimester		2nd Trimester		3rd Trimester	
	Number of GDM Pts	Percentage	Number of GDM Pts	Percentage	Number of GDM Pts	Percentage
<18.5	0	0%	0	0%	0	0%
18.5-24.9	3	21.4%	8	24.24%	6	19.35%
25-29.9	4	28.6%	17	51.51%	15	48.38%
>30	7	50%	8	24.24%	10	32.20%
Total	14	100%	33	100%	31	100%
P value	<0.001		<0.001		<0.001	

There was positive correlation between increasing BMI and increase in incidence of GDM in all three trimesters. (p< 0.05).

Table-5: Distribution of GDM cases according to risk factors

Risk factors	Total	GDM	Percentage	P value
Obesity	26	25	96.15%	<0.001
Family H/O	62	37	59.60%	<0.001
GDM in Previous Pregnancy	9	6	66.70%	<0.001
Previous IUFD	4	2	50%	>0.05
Macrosomia	2	0	0	>0.05

Out of 300 women subjected to study total of 26 women were having BMI> 30 kg/m2, 62 were having family history of diabetes, 9 were having previous pregnancy with GDM, 4 were having previous history of IUFD/neonatal death, 2 were having macrosomia. Many were having more than one risk factor. There was correlation between risk factors and increase in incidence of GDM (p value <0.001) and significant correlation with risk factors like obesity, GDM in previous pregnancy, family history of GDM (p <0.001). In present study 54 (69.2%) GDM patients had risk factors, 24 (30.8%) GDM patients had no risk factors. Hence universal screening is recommended.

Discussion

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance with onset or recognition during pregnancy. Women with GDM are at increased risk of future diabetes predominantly type 2 diabetes mellitus (DM) and is also associated with increased risk of fetal morbidity and mortality. Ferrara et al showed the incidence at 7.5% in Asians, 5.6% in Hispanics, 4%, African American.[6] But this study showed a very high incidence of 25.3%. Anjalakshi et al in their study of 800 pregnant women diagnosed as GDM by 75g GCT glucose, irrespective of the last meal timings, found no statistically significant difference (P > 0.005)between the plasma glucose levels of GCT and WHO GTT performed in the GDM and normal glucose tolerant pregnant women.[7] Sensitivity and specificity was 100%. In Present study DIPSI, had sensitivity of 100% and specificity of 94.6%.

During the first trimester, 12 women had GDM (4%), 2 (0.7%) had overt diabetes. In second trimester 12.5%, third trimester 15.3% was newly diagnosed as GDM. We would have missed 4% of women who were diagnosed as GDM in 1st trimester and 15.3% women newly diagnosed as GDM in third trimester, if usual screening once done at 24-28wks. Therefore screening for GDM in all trimesters is equally important.

Sheshiah et al noted increase in the prevalence of GDM in their study and attributed it to increased BMI, as high maternal weight is associated with a substantially higher risk of GDM.[3] Present study association between risk factors and GDM was statistically significant p <0.05. Risk factors taken in this study were obesity, previous history of GDM, family history of DM, history of macrosomia (>4kg) in previous deliveries, previous history of IUFD, still birth, early neonatal death P value <0.05 statistically significant in risk factors like obesity, family history of DM, previous history of GDM. Out of total 78 patients who were diagnosed as GDM, 54(69.2%) had some or other risk factors, 24 (30.8%) patients had no risk factors. Hence present study shows the need for universal screening.

Though in the present study the association of GDM with the age groups showed no statistical significance in

all the three trimesters (p>0.050), In clinical practice, maternal age of ≥25 years should be adopted instead of ≥35 years or 40 years as a risk factor for the development of GDM.[8] In the UK, Sebire studied the effects of maternal obesity on pregnancy outcomes in a London cohort of 287, 213 women. Since then, similar reports have been published from Wales and Scotland.[9] Risk factors for GDM include a high BMI, excessive weight gain or low physical activity during pregnancy, high dietary intake of polyunsaturated fats, glucose intolerance or the birth of a large baby in previous pregnancy, and a family history of diabetes. The Present Study showed a significant association between GDM ($p < 0.050$).

Conclusion

The DIPSI test used in the study for screening for GDM proved to be simple, less cumbersome, cost effective and easily acceptable to the patients. Screening for GDM in all three trimesters is equally important. 30.8% of patients with no risk factors had GDM. Hence universal screening is recommended.

The present study also showed association of increasing BMI with increasing incidence of GDM, although it did not show positive correlation of increasing age with the incidence of GDM. This evidence is enough to evaluate the efficacy of subjecting all the pregnant patients to test for screening for GDM in all three trimesters and this test should become the part of routine antenatal investigations.

Consent

Written informed consent was obtained from the patients for publication of this research study.

References

1. Seshiah V, BalaijV, Madhuri S Balaji, Panneerselvam A, Kapur A. Pregnancy and Diabetes Scenario around the World: India. Int J Gynaecol Obstet. 2009 Mar; 104 suppl 1: S35-8. doi: 10.1016/j.ligo.2008.11.035

2. Seshiah V, Balaji V, Balaji MS, Panneerselvam A, Arthi T, Thamizharasi M et al. Prevalence of GDM in South India (Tamil Nadu)-a Community based study. J Assoc Physicians India. 2008 May; 56: 329-33.

3. Zargar AH, Sheikh MI, Bashir MI, Masoodi SR, Laway BA, Wani AI et al. Prevalence of gestational diabetes mellitus in Kashmiri women from the Indian subcontinent. Diabetes Res Clin Pract. 2004 Nov; 66(2):139-45

4. Sheshiah V, Balaji V, Balaji MS et al. One step for Screening and diagnosis of GDM. J. Obstet Gynecol. India 2005; 55(6) 525-29.

5. Sheshiah V, Das Ak, Balaji V et al. Gestational diabetes mellitus -Guidelines. J Assoc Physicians India. 2006 Aug; 54(8):622-8.

6. Ferrara A, Hedderson MM, Queensberry CP, Selby J. Prevalence of GDM detected by NDDG or the C & C plasma glucose thresholds. Diabetes care 2002 Sep; 25(9): 1625-30. PMID:12196438 [PubMed - indexed for MEDLINE]

7. Anjalakshi, Balaji, Madhuri et al. A Single procedure to diagnose gestational diabetes mellitus. Acta Diabetol (2009) 46(1): 51-4. doi: 10.1007/s00592-008-0060-9. Epub 2008 Oct 2

8. Lao TT, HoLF, Chan BC, Leung WC. Maternal age and prevalence of Gestational diabetes mellitus. Diabetes Care. 2006 Apr; 29(4):948-9 . http://dx.doi.org/10.2337/diacare.29.04.06.dc05-2568

9. Bhattacharya S, Campbell DM, Liston WA, Bhattacharya S. Effect of Body Mass Index on pregnancy outcomes in nulliparous women delivering singleton babies. BMC Public Health. 2007; 7: 168. doi: 10.1186/1471-2458-7-168

How to cite this article?

Gayam S, Madhurima P, Paul S, Tallavajhula M. The validity of single step test (DIPSI) for screening for GDM in all trimesters of pregnancy. *Obs Rev: J obstet Gynecol* 2015;1(2):34-38. doi: 10.17511/joog.2015.i02.02.