

PROSPECTIVE STUDY TO DETECT GESTATIONAL DIABETES MELLITUS BY DIPSI – SINGLE STEP TEST

Gynaecology

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ABSTRACT

INTRODUCTION – The prevalence rate of Gestational Diabetes Mellitus (GDM) is said to reflect the prevalence of Impaired Glucose Tolerance (IGT) in young reproductive women as well as the background prevalence of Type-2 DM in the given population.

AIM'S AND OBJECTIVE - To detect gestational diabetes mellitus by DIPSI – single step test.

MATERIAL AND METHODS - This study was conducted in 200 patients coming to Pannadhy Rajkiya Mahila Chikitsalaya, RNT Medical College, Udaipur followed throughout their antenatal period in all three trimesters. The incidence and onset gestational diabetes mellitus in antenatal women using Single Step Diagnostic Test (DIPSI criteria by measuring venous plasma levels 2 hours after ingestion of 75 gm oral glucose).

RESULTS - In our study population 13.5% women were found to have Gestational Diabetes Mellitus (GDM) and 8% more having Gestational Glucose Intolerance (GGI). Out of that, 37.04% of GDM and 25% GGI were picked up in first trimester only. An incidence of GDM as 15 to 17%, out of that 17% cases were picked up before 16 weeks of gestation.

CONCLUSION - Finally we can say, a short term intensive care gives a long term pay off in the primary prevention of obesity, impaired glucose tolerance and diabetes in the offspring, as preventive medicine starts in utero.

KEYWORDS

Gestational Diabetes Mellitus (GDM), Gestational Glucose Intolerance (GGI), Impaired Glucose Tolerance (IGT), Diabetes in pregnancy study group India (DIPSI).

INTRODUCTION

India is known as the Diabetic Capital of the world. The prevalence rate of Gestational Diabetes Mellitus (GDM) is said to reflect the prevalence of Impaired Glucose Tolerance (IGT) in young reproductive women as well as the background prevalence of Type-2 DM in the given population. Prevalence rate of GDM in developed countries ranges from less than 1 to 20%. In developing countries like INDIA, it ranges from 0.6 to 18.9%.¹

Gestational Diabetes Mellitus (GDM) is defined by WHO as “Carbohydrate intolerance resulting in hyperglycemia of variable severity with onset or first recognition during pregnancy”.² The definition applies regardless of whether treatment is diet modification alone or in combination with insulin. It does not rule out the possibility that unrecognized glucose intolerance may have antedated the pregnancy or begun concomitantly with the pregnancy.

Normal pregnancy has been characterized as a Diabetogenic state due to changes in pattern of insulin secretion and sensitivity, thus pregnancy induces progressive changes in maternal carbohydrate metabolism. A pregnant woman who is not able to increase her insulin secretion to overcome the insulin resistance that occurs during pregnancy tends to develop gestational diabetes mellitus.³

The maternal metabolic adaptation is to maintain:-³

- Fasting venous plasma glucose levels of 74.5 ± 11 mg/dl.
- Postprandial levels of 108.7 ± 16.9 mg/dl.

There is a wide variation in the prevalence rate of GDM mainly due to ethnic differences, different screening procedures and criteria used, maternal age, parity, prepregnant weight and BMI and whether the studied populations reside in rural or urban areas.

Ethnically Indian women have high prevalence of diabetes and the relative risk of developing GDM in Indian women is 11.3 times compared to white women necessitating universal screening for glucose intolerance during pregnancy in India. GDM is overlooked in 1/3 of the women when selective screening is performed and when this is applied to millions of reproductive age group women in India, we are missing a lot of women likely to have glucose intolerance.⁴

When to Screen

In India 17% of cases of GDM are diagnosed before 16 weeks of gestation indicating the significance of early screening in first trimester

(ICOG FOGSI 2011).

The usual recommendation for screening between 24 to 28 weeks of gestation, the chances of detecting unrecognized type 2 DM before pregnancy (pre GDM) is likely to be missed. Hence, recent concept is to practice early screening in first trimester. The pregnant women found to have normal glucose tolerance (NGT) in first trimester should be re-tested for GDM at 24 - 28 weeks and at 32nd - 34th weeks and also in later weeks if necessary, particularly when rapid maternal weight gain occurs or fetal macrosomia is suspected.⁵

In 2008 a large randomized controlled study including 9 countries and 15 divisions called as HAPO study was designed to demonstrate the relationship between maternal hyperglycemia less severe than overt diabetes mellitus and pregnancy outcome.⁶ After the release of HAPO study, a group designated as international association of diabetes in pregnancy study groups (IADPSG) was created to formulate recommendations for glucose tolerance testing in pregnancy based on the results of the HAPO study.⁷ They concluded that there are centre to centre differences in prevalence of GDM due to variations in the maternal age, BMI, family history of diabetes and thus defined threshold values for diagnosis of GDM based on 75 gms OGTT.

Compared to selective screening, universal screening will help in early detection and timely management of GDM improves maternal and neonatal prognosis. Hence universal screening for GDM is essential as it is generally accepted that women of Asian origin and especially Indians are at higher risk of developing GDM and subsequent type 2 diabetes.⁵ Performing universal screening using traditional OGTT (0,1,2,3 hrs value) was cumbersome and time consuming and many patients were lost in followup because of that. Thus a single step diagnostic procedure was accepted to perform universal screening.

The present study followed the DIPSI (Diabetes in pregnancy study group India) guidelines for screening.

DIPSI Recommended Method - Single Step Test (Diabetes in Pregnancy Study Group India)⁵

Includes challenging all antenatal women with 75 gm of oral anhydrous glucose at their 1st trimester visit, irrespective of their fasting status and then measuring venous plasma glucose levels after 2 hrs.

- Blood sugar >140 mg/dl - serves as screening and diagnostic of **Gestational Diabetes Mellitus (GDM)**.
- Blood sugar- 120 to 140 mg/dl - termed as **Gestational Glucose Intolerance (GGI)**.

Blood sugar <120 mg/dl - **Normal**.

Rationale

After a meal, normal glucose tolerant women would be able to maintain euglycemia despite glucose challenge due to brisk and adequate insulin response. Whereas a women with GDM who has impaired insulin secretion, her glycemic levels increases with a meal and with glucose challenge, the glycemic excursion exaggerates further. This cascading effect is advantageous as this would not result in false positive diagnosis of GDM.⁸

AIMS AND OBJECTIVES

- To determine the incidence of GDM in the antenatal patients using a single step diagnostic test.
- To determine the onset of GDM with respect to period of gestation.
- To evaluate the role of timely intervention in management of GDM.

MATERIAL AND METHOD

This hospital based descriptive randomized clinical study was conducted in Department of Obstetrics and Gynecology, Pannadhay Rajkiya Mahila Chikitsalaya, RNT Medical College, Udaipur during the year 2019-20.

SAMPLE SIZE

Sample size of present study was 200 cases and these cases were followed throughout their antenatal period in all three trimesters.

DIPSI RECOMMENDED METHOD - SINGLE STEP TEST (DIABETES IN PREGNANCY STUDY GROUP INDIA):

Includes challenging all antenatal women with 75 gm of oral anhydrous glucose at their 1st antenatal visit, irrespective of their fasting status and then measuring venous plasma glucose levels after 2 hrs.

- Blood sugar >140 mg/dl - serves as screening and diagnostic of Gestational Diabetes Mellitus (GDM).
- Blood sugar- 120 to 140 mg/dl - termed as gestational glucose intolerance (GGI).
- Blood sugar <120 mg/dl - normal.

These patients were followed in their 2nd trimester at 24-28 wks and in 3rd trimester at 32-34 wks gestational age.

INCLUSION CRITERIA

- All the pregnant women in their 1st trimester, attending antenatal clinic were enrolled in this study. These were then followed in 2nd and 3rd trimester accordingly.
- Singleton pregnancy
- Pregnant women of any parity or gravidity

EXCLUSION CRITERIA

- Antenatal women with pregestational Diabetes Mellitus were excluded.
- Cardiac/hepatic/Respiratory and other pre-existing medical disorders.
- Taking drugs that alter glucose metabolism.

RESULTS

On the basis of plasma glucose values obtained using Single Step Diagnostic Test (DIPSI Criteria), all 200 cases were divided into 3 groups according to the DIPSI Guidelines. 157 (78.50%) cases belong to the NGT group, 16 (8.00%) cases of GGI and 27 (13.50%) cases of GDM.

Distribution of cases using a Single step Diagnostic test (DIPSI Criteria)

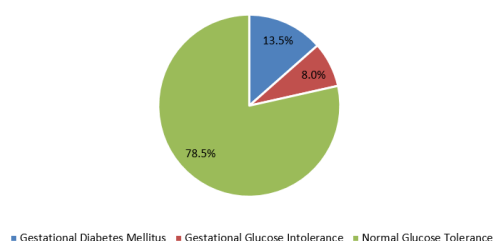


Table – 1: Detection of GDM & GGI cases according to trimester

Trimester	GDM cases	GGI cases
First trimester	10	4
Second trimester	9	6
Third trimester	8	6
Total	27	16

4 (25%) cases of GGI detected in first trimester, 6 (37.50%) cases were detected in second trimester and 6 (37.50%) cases were detected in third trimester. 4 Cases were detected in first trimester screening which shows the significance of early screening which would have been missed and would have been detected at routine 24-28 wks of screening thus delaying commencement of treatment and affecting the perinatal outcome.

Out of 27 positive GDM cases, 10 (37.04%) were identified in first trimester, 9 (33.33%) cases were identified in second trimester and 8 (29.63%) cases were identified in third trimester indicates the significance of screening in first trimester itself.

Table – 2: Distribution of cases according to their First visit weight and Trimester wise weight

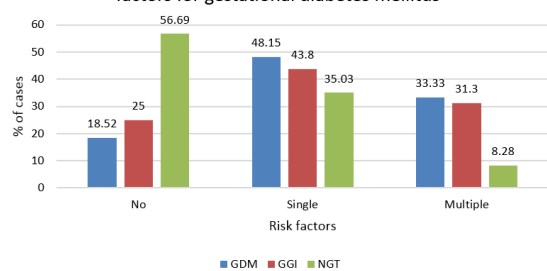
		First Visit Weight	I Trimester (10-12 wks)	II Trimester (24-28 wks)	III Trimester (36-38 wks)
GDM	N	26	26	26	26
	Mean	51.96	54.38	59.00	64.19
	SD	6.64	6.63	6.92	6.95
GGI	N	16	16	16	16
	Mean	50.13	52.44	56.88	62.75
	SD	3.26	3.12	2.47	2.44
NGT	N	158	158	158	158
	Mean	49.38	52.06	56.73	62.27
	SD	4.49	4.67	4.69	5.12
Total	N	200	200	200	200
	Mean	49.78	52.39	57.04	62.56
	SD	4.80	4.91	4.94	5.26
P value Ls		0.037S	0.080NS	0.093NS	0.224NS

On applying statistical analysis tests it was found that First Antenatal Visit weight was significantly more in GDM cases. NO significant difference was observed according to weight among the trimester wise cases. The table shows mean weight of patients at first antenatal visit. 27 cases of GDM had a mean weight of 51.96 kg, 16 cases of GGI had a mean weight of 50.13 kg and 157 cases of NGT had a mean weight of 49.38 kg.

It was observed that mean weight of GDM patients was significantly more than the NGT cases. If we see the weight of the studied patients trimester wise, average wt for 27 GDM cases was found to be 54.38 kg in first trimester, 59.00 kg in second trimester and 64.19 kg in third trimester. For 16 cases of GGI the mean first trimester weight was 52.44 kg, 56.88 kg in the second trimester and 62.75 in the third trimester. For 157 cases of NGT mean first trimester weight was 52.06 kg, 56.73 kg in the second trimester and 62.27 in the third trimester.

No significant difference was observed in mean trimester wise weight of all the three groups. Thus it can be concluded that if the patients of GGI and GDM are managed effectively chances of complications are less.

Distribution of cases according to number of risk factors for gestational diabetes mellitus



Among 27 cases of GDM, majority of them were having risk factor for GDM i.e. 13 cases with single risk factor and 9 cases with multiple risk

factors still 5 cases were identified without any risk factor for GDM. Similarly, 7 cases of GGI were having single risk factor and 5 cases

were having multiple risk factor for GDM 4 cases were identified without any risk factor.

Table –3: Distribution of cases according to Obstetric Complications

Any Obstetric Complication	GDM (N=27)		GGI (N=16)		NGT (N=157)		Total (N=200)		Chi square test
	No.	%	No.	%	No.	%	No.	%	P Value LS
Oligohydromnios	3	11	0	0	14	8.92	17	8.5	0.386NS
Polyhydromnios	8	29.63	5	31.3	10	6.37	23	11.5	<0.001S
Macrosomia	1	3.7	2	12.5	6	3.82	9	4.5	0.72NS
IUGR	2	7.4		0	5	3.18	7	3.5	0.390NS
Rapid Weight gain in Third trimester	0	0	0	0	2	1.27	2	1	0.758NS
Gestational HTN	6	22	2	12.5	16	10.19	24	12	0.206NS
Preeclampsia	2	7.4	0	0	9	5.73	11	5.5	0.567NS
PREMATURITY	3	11	1	6.25	9	5.73	13	6.5	0.560NS
IUFD	0	0	0	0	1	0.637	1	0.5	0.870NS

By applying chi square test in all of the complications separately in all 3 groups, it was found that only polyhydromnios had a significant association with glycemic levels of the patients ($p < 0.001$) and differences in other complications in the 3 groups were non significant ($p > 0.05$).

Polyhydromnios was observed in 8 (29.63%) of cases of GDM, 5 (31.30%) cases of GGI and 10 (6.37%) cases of NGT which shows GDM and GGI were significantly complicated with polyhydromnios.

Oligohydromnios was observed in 3 (11.11%) of cases of GDM, 0% cases of GGI and 14 (8.92%) cases of NGT. Pre eclampsia was found in 2 (7.40) % of GDM and 9 (5.93%) % of NGT. Prematurity was observed in 3 (11.11%) of cases of GDM, 1 (6.25%) of cases of GGI and 9 (5.73%) of cases of NGT.

Table –4 : Distribution of cases according to Mode of Delivery

Mode of delivery	GDM(N=27)		GGI(N=16)		NGT(N=157)		Total(N=200)	
	No.	%	No.	%	No.	%	No.	%
FTCS	16	59.26	6	37.5	34	21.66	56	28
FTNVD	8	29.63	9	56.25	111	70.70	128	64
PTCS	2	7.41	0	0	7	4.46	9	4.5
PTVD	1	3.70	1	6.25	5	3.18	7	3.5

Above table shows that 18 (66.67%) cases of GDM, 6 (37.50%) cases of GGI and 41 (25.72%) cases of NGT underwent LSCS either full term or preterm.

9 (33.33%) cases of GDM, 10 (62.50%) cases of GGI and 116 (73.88%) cases of NGT had either full term or preterm normal delivery.

Table –5: Distribution of cases according to neonatal complications

Complications	GDM		GGI		NGT		Total		Chi square test
	No.	%	No.	%	No.	%	No.	%	P value LS
Hypoglycemia	3	11.11	0	0	0	0.00	2	1	<0.001S
LBW	2	7.41	0	0	4	2.55	4	2	0.3NS
Prematurity	3	11.11	1	6.25	10	6.37	1	0.5	0.667NS
Macrosomia	2	7.41	2	12.5	6	3.82	10	5	0.26NS
Still Birth	0	0.00	0	0	2	1.27	1	0.5	0.75NS

Only 3 (11.11%) newborns of GDM mothers developed hypoglycemia. ($p < 0.001$). 2 (7.41%) newborns of GDM positive mothers were low birth weight with a p value of 0.3 which is non significant. 2 (7.41%) case of GDM positive mother had macrosomia which was non significant. 3 (11.11%) newborns of GDM positive mother and 1 (6.25%) of newborn born to GGI mother had prematurity. P value was non significant for both.

Table –6: Follow up of GGI cases After 2 weeks of MNT (n = 16)

	NGT		GGI		GDM	
	No.	%	No.	%	No.	%
Repeat DIPSI Test	12	75	4	25	0	0

All the 16 cases of GGI when followed up after 2 wks of MNT, 12 (75%) cases responded well to MNT and reverted back to NGT, while 4 (25%) cases continued as GGI and none of them progressed to GDM.

Table –7: Follow up of GDM cases after 2 weeks of MNT (n = 27)

	FBS				2 hr Post Meal			
	FBS <90		FBS >90		<120		>120	
	No.	%	No.	%	No.	%	No.	%
GDM (N=27)	25	92.59	2	7.41	25	92.59	2	7.41

When 27 cases of GDM were subjected to MNT, and when they were reviewed after 2 weeks with their fasting and 2 hours post meal plasma glucose levels, it was found that majority of them i.e. 25 cases were in euglycaemic range and only 2 cases were not controlled by MNT and further needed insulin therapy.

DISCUSSION

In the present study 200 cases were taken which were challenged with 75 grams of glucose and plasma glucose levels were measured after 2 hrs (Single Step Diagnostic Test – DIPSI Criteria), out of which 27 (13.50%) cases were diagnosed Gestational Diabetes Mellitus, 16 (8.00%) cases were Diagnosed as Gestational Glucose Intolerance and 157 (78.50%) cases were found to be Normal Glucose Tolerance.

Incidence of Gestational Diabetes Mellitus

On the basis of plasma glucose values obtained using Single Step Diagnostic Test (DIPSI Criteria), all 200 cases were divided into 3 groups according to the DIPSI Guidelines. 157 cases belong to the NGT group, 16 cases of GGI and 27 cases of GDM.

Incidence of GDM (13.5%) in our study was comparable with the study done by V Balaji et al (2011)⁹ who identified 13.40% of GDM cases based on DIPSI Criteria by universal screening in Chennai, Tamil Nadu.

Preeti Wahi et al (2011) estimated incidence of GDM as 6.51% using single step criteria for screening in Jammu region.¹⁰ Results are also comparable with another study done by V Seshiah et al (2009), who found incidence of 13.90% in his study using WHO criteria for diagnosis in Chennai, Tamil Nadu.¹¹ Walter Plasencia et al (2011) found 4.95% of GDM cases universal screening by ADA criteria in London, UK.¹²

Onset of GGI with respect to period of gestation

Four cases of GGI were detected in first trimester, 6 cases were detected in second trimester and 6 cases were detected in third trimester. Four cases were detected in first trimester screening which shows the significance of early screening which would have been missed and would have been detected at routine 24-28 wks of screening thus delaying commencement of treatment and affecting the perinatal outcome.

Bagher Larijani et al (2004) identified 114 cases of GDM with blood sugar value cut off of 130 mg/dl and above and 100 cases with blood sugar cut off of 140 mg/dl and above indicating that 14 cases of GDM are identified extra by lowering threshold for screening.¹³

Franks PW et al (2006) found 19% risk of type 2 diabetes mellitus at 24 yrs of age in offspring's born to mothers who had third trimester plasma glucose level between 120-140 mg/dl.¹⁴

Mean first visit weight and trimester wise mean weight gain

27 cases of GDM had a mean weight of 51.96 kg, 16 cases of GGI had a mean weight of 50.13 kg and 157 cases of NGT had a mean weight of 49.38 kg. It was observed that mean weight of GDM patients was significantly more than the NGT cases. If we see the weight of the studied patients trimester wise, average wt for 27 GDM cases was found to be 54.38 kg in first trimester, 59.00 kg in second trimester and 64.19 kg in third trimester. For 16 cases of GGI the mean first trimester weight was 52.44 kg, 56.88 kg in the second trimester and 62.75 in the third trimester. For 157 cases of NGT mean first trimester weight was

52.06 kg, 56.73 kg in the second trimester and 62.27 in the third trimester. No significant difference was observed in mean trimester wise weight gain of all the three groups, Thus it can be concluded that if the patients of GGI and GDM are counseled and managed since beginning chances of complications like polyhydromnios, macrosomia, rapid weight gain are less.

Risk factors

Various risk factors were taken into account to determine the incidence of GDM in relation to presence of risk factors, namely Age > 25 yrs, Family History of DM, GDM in previous pregnancy, PCOS, Previous >2 spontaneous abortions, previous history of congenital malformations, prev history of IUFD, previous history of macrosomia. Among 27 cases of GDM, majority of them were having risk factor for GDM i.e. 13 cases with single risk factor and 9 cases with multiple risk factors still 5 cases were identified without any risk factor for GDM. Similarly, 7 cases of GGI were having single risk factor and 5 cases were having multiple risk factors for GDM 4 cases were identified without any risk factor.

Thus it can be clearly concluded that although presence of risk factors has a strong association with development of GDM, it may develop in absence of risk factor too. A large number of patients with risk factors were also there who did not develop GDM thus necessitating the need of test in every pregnant woman.

Obstetrics complications

Polyhydromnios was observed in 29.63% of cases of GDM, 31.30% cases of GGI and 6.37% cases of NGT which shows GDM and GGI were significantly complicated with polyhydromnios. Oligohydromnios was observed in 11.11% of cases of GDM, 0% cases of GGI and 7.01% cases of NGT which is lower than the expected value.

Prematurity was observed in 11.11% of cases of GDM, 6.25% of cases of GGI and 5.73% of cases of NGT which is again lesser than the expected value (20%). None of the patient from GDM group developed shoulder dystocia, chorioamnionitis, or any traumatic delivery which is a known complication of GDM. Thus it can be concluded that incidence of obstetrics complications were found higher in GDM compared to GGI and NGT.

Fetal Complications

It is evident that incidence of fetal distress was 29.63% in GDM cases, 31.30% in GGI cases and 10.83% in NGT cases, pointing that the incidence of fetal distress has been significantly associated with glycemic status of the patient.

Macrosomia was observed in 1 case of GDM, 2 cases of GGI and 5 cases of NGT which is lesser than expected incidence of 30-40%, thus signifying the role of timely management. This data suggest the need for early detection of GDM compared to late or undiagnosed GDM.

Postpartum complications of Mother

Only 3 cases of NGT developed wound sepsis, 1 case of NGT had PPH and none of the cases of GGI or GDM had any postpartum complication signifying the importance of timely management to maintain euglycaemia during intrapartum and postpartum period. Preeti Wahi et al (2011) identified 1 (1.4%) case of GDM developing PPH which is again non significant.¹⁰

Admissions to neonatal intensive care unit

8 (29.63%) neonates born to GDM mother, 1 (6.25%) neonate born to GGI mother and 15 (9.5%) neonates born to normoglycaemic mothers were admitted to NICU. This shows a significant rate of babies born to GDM mother getting admitted to NICU compared to normal glycemic mother. (p<0.009).

Our study was comparable to the study conducted by Turki Gasim et al (2012) who found 36 (16.4%) cases getting admitted to NICU.¹⁵

Early neonatal complications

Only 3 (11.11%) newborns of GDM mothers developed hypoglycaemia. Though its p value is significant but is much lesser than the expected value of 30-50%. 2 (7.41%) newborns of GDM positive mothers were low birth weight with a p value of 0.3 which is non significant. 1 (3.70%) case of GDM positive mother had macrosomia which was non significant. 3 (11.11%) newborns of GDM

positive mother and 1 (6.25%) of newborn born to GGI mother had prematurity. P value was non significant for both. 3 (11.11%) cases of GDM, 1 (6.25%) case of GGI and 8 cases of NGT had respiratory distress syndrome which was again non significant.

None of the newborn developed hypocalcaemia, hyperbilirubinemia or polycythemia which are the known complications of neonates of GDM positive mothers. This shows that timely and appropriate management helps in prevention of neonatal complications.

Insulin and MNT requirements

25 cases of GDM maintained euglycaemia after MNT and 2 (7.41%) cases required insulin therapy to achieve adequate glycaemic control. Results of our study were comparable to the study done by V Balaji et al (2011) who identified 19 (9.7%) cases of GDM requiring insulin along with MNT.⁹ On the contrary Preeti Wahi et al (2011) identified 26 (38.09%) cases of GDM requiring insulin along with MNT.¹⁰

CONCLUSION

Various compelling reasons for addressing GDM include the elevated risk of adverse pregnancy outcomes, including maternal and perinatal mortality, obstructed labour, infections, spontaneous abortions, congenital anomalies and macrosomia. Timely action taken now in the form of screening all pregnant women for glucose intolerance, achieving euglycemia in them and ensuring adequate nutrition may prevent in all probability the vicious cycle of transmitting glucose intolerance from one generation to another.

Finally we can say, a short term intensive care gives a long term pay off in the primary prevention of obesity, impaired glucose tolerance and diabetes in the offspring, as preventive medicine starts in utero. "Addressing GDM thus constitutes a window of opportunity for early intervention and reduction of the future burden of type 2 diabetes mellitus".

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