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ROLE OF ORAL GLUCOSE TOLERANCE TEST IN THE DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS

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ABSTRACT

BACKGROUND: Clinical recognition of Gestational Diabetes Mellitus is important because proper recognition and intervention can reduce the well described GDM associated perinatal morbidity and mortality. The frequency of GDM is highly variable and generally reflects the underlying pattern of NIDDM in the particular population. There is no universal agreement on the screening strategies and diagnostic criteria of GDM. Hence, there is a need to identify a single step procedure which serves both as a screening as well as a diagnostic tool for gestational diabetes mellitus. AIMS AND OBJECTIVES: To screen all the antenatal women seeking antenatal care, to detect cases of GDM. To diagnose GDM cases early in pregnancy. MATERIALS AND METHODS: The study was conducted in the Department of General Medicine, Sri Aurobindo Medical College & PG Institute-Indore, between March 2023 and February 2024 on 1595 pregnant women attending the antenatal clinic of the gestational age 16 wks, between 24-26 wks, 32-36 wks and 38 wks irrespective of maternal age and gravidity and presence or absence of clinical or historic risk factors for gestational diabetes mellitus are considered for inclusion in the study. Women who are known cases of Type II diabetes mellitus and those in labour are excluded. RESULTS: In the 1595 women taken for study the incidence of GDM was 4.3%.

INTERPRETATION AND CONCLUSION: In the Indian context with a high prevalence of GDM and where universal screening is mandatory, it is feasible and conducive to opt for the 75g OGTT. The two step procedure of screening with 50g GCT and then diagnosing GDM based on the cutoff values with 100g or 75g is not practical as the pregnant women have to visit the clinic twice and the number of blood samples drawn vary from 3 to 5 which the women resent. Hence for universal screening a single test with 75g of oral glucose and diagnosing women with >140mg% as GDM is recommended.

KEYWORDS: *Gestational Diabetes Mellitus; Oral Glucose Tolerance Test; Insulin; Carbohydrate.*

INTRODUCTION

Gestational diabetes mellitus is "Carbohydrate intolerance of variable severity with the onset and first recognition during the present pregnancy". Virtually all new cases of diabetes in pregnancy are a transient form of type 2 diabetes. A small proportion of cases of denovo diabetes are found to persist after pregnancy. Most of these are type II DM. However, rarely Type I DM will arise during pregnancy simply as a matter of coincidence.[1]

GDM is a controversial clinical entity believed to be unmasking of a compensated metabolic abnormality characterized by relative insulin deficiency and increased insulin resistance. Pregnancy is the special situation as far as the pregnancy is concerned in which potential adverse effects on the fetus and mother is paramount

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importance and should be clearly identified.[2]Jarrett[3] wrote that GDM is non entity whose only clinical association is with an increased risk of mother subsequently becoming diabetic. Hunter and Milner[4] stated that "Gestational diabetes is a diagnosis still looking for a disease whereas Beard and Hoet5 concluded that GDM is a clinical entity associated with increased fetal and maternal morbidity. It has been demonstrated that perinatal and maternal morbidity among GDM can be reduced with application of a systematic approach to the identification and management of the disease. Indian data on GDM is scant and does not give the actual picture. India falls under moderately high risk group and with the advent of western life style, incidence of type II DM is raising precipitously. So number of women with GDM is also raising, hence the need for this study. Inspite of plenty of research papers over the years, still lot of controversies remain, regarding type of screening, universal or selective, which diagnostic test to follow and ideal cutoff levels.

This study is done to find out the prevalence of GDM in our hospital, to find out a one step procedure, which serves both as a screening as well as a diagnostic tool for gestational diabetes mellitus.

Aims and Objectives

To screen all antenatal women seeking antenatal care to detect cases of gestational diabetes mellitus. To diagnose GDM cases early in pregnancy.

Background

Historic Perspective: Diabetes is one of the oldest diseases known to mankind. Though there is a wealth of data on diabetes in general, diabetic pregnancy is poorly mentioned and studied at least till 19th Century. The first case of Fredecia Page 22, who was admitted to the Berlin infirmary at seventh month into her fifth pregnancy in 1823 is the first case of GDM in the literature. In 1882 – Mathews Duncan presented a paper entitled "On Puerperal diabetes". The real break thorough in diabetic pregnancy came in 1922 with Best and Banting's invention of insulin. It changed the gross fetal and maternal mortality and morbidity associated with diabetic pregnancy. The management of diabetic pregnancy was an art and science developed in the hands of pioneers like Dr. Elliott Proctor Joslin of Boston. Later Dr. Priscilla White who joined him continued the legacy. It the following years, knowledge about diabetes mellitus has grown drastically. And diabetic women now have a pregnancy outcome that can be compared to non diabetic. In the meanwhile, it was noted that since 5% of women were diabetic by the age of 50 years there were 50 future diabetics in every thousand antenatal patients. It was noticed that these women had increased perinatal mortality.[5]

Gilbert and Dunlop used the term predicaments to refer to the time interval before the diagnosis of diabetes and the retrospective analysis of the obstetric history in overt diabetics[6] they found a fetal loss of 50% for the two years preceding diagnosis.Jackson[7] (1952) stated that predicaments was a clinical diagnosis based on the previous obstetric history.

Definition of GDM: Considerable argument prevails over this. The one adapted by International Workshop conference on Gestational Diabetes is as follows: Carbohydrate intolerance of variable severity with onset or first recognition during the present pregnancy. The definition applies irrespective of whether or not insulin is used for the treatment or the condition persists after pregnancy".[8]

Table 1 Classification of Diabetes complicating pregnancy by White (1978)

Class	Onset	FPG	2-4 hour PPG	Therapy
A1	Gestational	< 105mg/dl	<120mg/dl	Diet
A2	Gestational	> 105mg/dl	> 120mg/dl	Insulin
Class	Age of onset	Duration	Vascular disease	Therapy
B	> 20	< 10	None	Insulin
C	10-19	10-1 9	None	Insulin

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D	Before 10	> 20	Benign retinopathy	Insulin
F	Any	Any	Nephropathy	Insulin
R	Any	Any	Proliferative retinopathy	Insulin
H	Any	Any	Heart	Insulin

Incidence and prevalence

The incidence of GDM ranges from 0.2%-12% depending on the population studied.[9,10] Incidence is high in populations with high incidence of Type 2 DM As is the case with Type 2 DM the frequency of GDM is increasing. During 2 decades of observation from one centre for instance, the prevalence of GDM was found to have tripled from 3%-9%.[11]

In Indian context our women have 11 fold increased rate of developing intolerance during pregnancy when compared to Caucasian[12] women. Among the ethnic groups in South Asian countries Indians have the highest rate of GDM.[13]The recent data shows 6.5% prevalence of GDM in our country.[14] The lowest prevalence GDM is from South India. This is in contrast with the situation known to exist in migrant Indian communities in other parts of the world.

Table 2 Incidence of GDM according to country of birth.

Australia, New Zealand	3%
UK	2.3%
China, Singapore, Hong Kong, Philippines, Malaysia	8.3%
Vietnam	4.3%
Greece	5.4%
Yugoslavia, Czech, USSR, Poland	8.5%
Lebanon, Egypt, Jordan, UAE	5.1%
Turkey	4.9%
Sri Lanka, Pakistan, India, Bangladesh	8.2%
Malta	10.6%
Others	4.7%

Risk factors associated with GDM:- Maternal age**,** Family history of type 2 DM ,Non white ethnic origin**,** Obesity**,** Smoking**,** Increased weight gain in early childhood**,** Polycystic ovary syndrome**,** Previous large infant > 95th percentile, Previous unexplained still birth, Glucosuria, H/o congenital anomaly, H/o prematurity, Polyhydramnios, H/o GDM in previous pregnancy, H/o unexplained neonatal death.

Clinical profile of Women with GDM

A recent studies by Jang et al[15]in Korea the characteristics of diabetes with and without diabetes. Those with diabetes were older, had pre pregnancy weight, higher BMI, higher parity and a higher frequency of known diabetes in the family. These results tend to confirm to the traditional risk factors for NIDDM.

Table 3 Clinical Profile of Women with GDM

Risk Factors	GDM	Normal Controls
Number of patients	80	3432
Age	31.7±4.0	28.9
Height, (cms)	158.1±4.8	159
Pre pregnancy weight	56.4±9.2	51.6
BMI(Kg/m)	22.6±3.4	20.2
Obesity(BMI >30kg/m2)	7(8.8%)	39(1.1%)
Weight	65.3±10.2	60

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Plasma glucose(mg/dl)	189.5	113.5
Parity	0.6	0.4
Family history of diabetes	28(35%)	528(15.5%)

Gestational Diabetes Mellitus

GDM typically develops during second half of pregnancy in parallel with the development of insulin resistance. Nevertheless insulin resistance is unlikely to be the cause because

1. To produce glucose intolerance in the presence of a healthy endocrine pancreas, insulin resistance needs to be severe. The insulin resistance in GDM never approaches the degree of insulin resistance seen in type B insulin resistance.

2. All pregnant women become insulin resistant but less than 10% will have GDM.[16]So these patients in addition should have defective secretion

In support of this hypothesis Buchanan and coworkers found that 1st phase insulin response to IV glucose was significantly decreased in women with GDM compared with normal pregnant women.[17]

Similarly Burstman and colleagues (1995)[18] tested 32 pregnant women with both the 75g OGTT and the 100g 3h OGTT. Despite a strong positive correlation between the results of the two tests, the glucose values of the 100g OGTT were significantly higher than those of the 75g OGTT. The One step 2h75 OGTT should be used for Indian population. It may also be useful in patients with a prepregnancy diagnosis of IGT or those with multiple risk factors.[18]

The two step procedure which is currently followed in India with 50gram GCT and then diagnosing GDM based on cutoff values with either 100gram or 75gram OGTT is not practical as the pregnant women have to visit the clinic at least twice and the numbers of blood samples vary from three to five which the women resent. Hence for Universal screening, Seshaiah V et al suggest that a single test with 75 gram OGTT instead of the two step procedure which is currently followed in India with 50gram GCT and then diagnosing GDM based on cutoff values with either 100gram or 75 gram OGTT. This method serves both as one   step screening and diagnostic procedure and is easy to perform besides being economical. Recently, the Hyperglycemia and Adverse pregnancy outcomes (HAPO study) which is a large (n=25000) prospective study on GDM worldwide in 16 centres has also adopted the 75g OGTT one step approach for screening and diagnosing GDM. Final results are awaited and results are likely to be more in favour of this study.

MATERIAL AND METHODS

This is a randomized study to study the role of one step oral 75 gm OGTT for the screening and diagnosing of GDM in pregnancy. The study was conducted in the Department of General Medicine, Sri Aurobindo Medical College & PG Institute-Indore, between March 2023 and February 2024.

Study design:- The study was a prospective randomized controlled clinical trial. There were a total number of 1595 pregnant women who were randomly picked up for universal screening.

Selection criteria: Inclusion criteria:-All patients coming for ANC checkups. Their duration of pregnancy should be: 16 weeks, 24-26 weeks, 32-36 weeks, 38 weeks.

Exclusion criteria:- Known cases of Type 2 diabetes mellitus, Patients in labour.

Procedure: The test is both diagnostic and a screening procedure. The patient need not be fasting. On arrival to the OPD patient is offered 75gm glucose (provided by the hospital pre   measured) to be consumed at one time or within 5-10mins. Blood is withdrawn for blood sugar level estimation after 2hrs using the autoanalyzer. Urine examination is done after 2 hours.

STATISTICAL METHODS: Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean $\pm$ SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. Chi-square test has been used to find the significance of study parameters on categorical scale. Sensitivity /specificity

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/PPV/ NPV has been calculated to find the effectiveness of 75 gm OGTT. Chi-Square Test, Descriptive statistics, T- test

Significant figures
+   Suggestive significance (p value: 0.05<p<0.10)
*   Moderately significant
**   Strongly significant
(p value: 0.01<p ≤ 0.05) (p value: p≤0.01)
Statistical software: The Statistical software namely SPSS 13 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

A prospective study was carried out on 1595 pregnant women of 16 weeks, 24-26 weeks, 32-36 weeks and 38 weeks of gestation during the time period of March 2011 to February 2012 selected and only according to the selection criteria listed in materials and methods and the result were analyzed.

Acceptability

Among 1595 patients only 6 patients had complaints of nausea and vomiting.

Demographic characteristics: The mean age of the study population is 24.21 ± 3.50 yrs. The age distribution of the study population is shown in the following table and figure.

Table 4: Age distribution of patients

Age	No. of patients	Percentage
17-21	300	18.81
22-26	898	56.30
27-31	318	19.94
32-34	79	4.95
Total	**1595**	**100**

Table 5 Association of Incidence of GDM with age

Age	Screened negative	Screened positive	P-value
17-21	295	5	0.402
22-26	893	18	0.331
27-31	284	26	0.204
32-34	54	20	0.152
Total	**1526**	**69**	

P-value for all age groups is more than 0.05 so, age does not differ in patients screened positive or negative for GDM 67% of GDM patients were >26 yrs of age whereas only 25% of pregnant women in the study population were in the>26 age group. The incidence of GDM increases with age.

Table 6 Distribution of patients according to BMI

BMI	No. of patients	Percentage
20-25	975	61.1
26-31	529	33.2
32-36	91	5.7
TOTAL	1595	100

Table 7 BMI distribution in GDM patients

BMI	No. of patients screened negative	Patients screened positive	P-value
20-25	956	19	0.45
26-31	500	29	0.03
32-36	70	21	0.01
Total	**1526**	**69**	

More than 72% of GDM patients fell in the BMI category of >25 kg/m^2 as compared to only 39% in the total population which is statistically significant. 30% of GDM population were in >31kg/m^2 category as compared to 5% of the total population which is again statistically significant.

Table 8 Prevalence of risk factors in GDM Patients

	GDM			
	Screened negative		Screened positive	
Risk factors	No.of Pts.	Percentage	No.of Pts.	Percentage
ABORTIONS	40	10.0	29	12.0
C.A0MALY	60	15.0	09	4.0
PRETERM DELIVERY	53	13.0	16	7.0
IUD	52	13.0	17	7.0
MACROSOMIA	51	13.0	18	8.0
POLYHYDRAMIOS	51	13.0	18	8.0
OBESITY	19	5.0	50	21.0
PREV.GDM	59	15.0	10	4.0
F.H.GDM	44	11.0	25	11.0
GLYCOSURIA	27	7.0	42	18.0
TOTAL	405	100	234	100

CHI-square p-value for risk factors is 0.0001, indicating there is high association between risk factors and development of GDM.

Previous adverse obstetric outcome, previous history of GDM, polyhydramnios, recurrent vaginal infections, obesity and family history of DM are important risk factors which are associated with GDM

Table 9 Association between GDM and Hba1c

	HBA1c		Total
	HBA1c<6.0	HBA1c>6.0	
Screened negative	0	1526	1526
Screened positive	51	18	69
TOTAL	51	1544	1595

Chi-square p-value is 0.0001, indicating that there is high association between GMD and HBA1c

DISCUSSION

The concept of Gestational Diabetes goes back at least to 1946. The importance of Gestational diabetes mellitus is that two generations, the women herself as are the children are at risk of developing diabetes in the future. Increasing maternal carbohydrate intolerance in pregnant women is associated with graded increase in adverse maternal and fetal outcomes.

Ethnically Indian women have high prevalence of diabetes. Over the next 2-3 decades there will be 80 million reproductive age women with Diabetes in world, of this 20 millions will be in India alone, creating potential

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for extremely high rates of maternal and infant mortality[19]. Indian women especially have eleven fold increase in developing gestational diabetes compared to Caucasian women.

Identification and systematic management of the disease reduces both maternal and perinatal morbidity. Hence universal screening during pregnancy has become important in our country. For this we need a simple procedure which is economical and feasible.

Single step 75gm oral glucose serves both screening and diagnostic procedure[20]. Despite more than 30 years of research there is no consensus regarding the optimal approach to the screening for gestational diabetes. A short term intensive care gives a long term pay off in the primary prevention of obesity, IGT and diabetes in the offspring, as the preventive measures starts in intrauterine life.

The two step procedure of screening with 50g GCT and then diagnosing GDM based on the cutoff values with 100g or 75g is not practical as the pregnant women have to visit the clinic twice and the numbers of blood samples drawn vary from 3 to 5 which the women resent. Hence, for universal screening a single test with 75g of oral glucose and diagnosing women with >140mg% as GDM is recommended. This method recommended by Seshaiah et al[21] serves both as a one step screening and diagnostic procedure and is easy to perform besides being economical.

CONCLUSION

1595 pregnant attending the antenatal clinic in our hospital at 16 weeks, 24-26 weeks, 34-36 weeks and 38 weeks of gestation were studied. This prospective study was done to know the incidence of GDM in our setup and to find the feasibility of a single step approach in the screening and diagnosis of GDM in our context.

The mean age of the study population was 24.2 ± 3.50 yrs.20 % of the study population had risk factors for GDM. Most of the pregnant women accepted the test readily and no adverse effects were observed. 4.3 % of the study population had positive screening for GDM. Women with glucose intolerance had significant risk factors like increased age, higher parity, and greater BMI compared to normal pregnant women. Present study concurs with the WHO recommendation of 2h 75g OGTT as one step procedure for both screening as well as diagnosis of GDM. Hence we recommend the adaptation of 75g OGTT for screening and diagnosis of GDM in all pregnant women especially in the Indian context.

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