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## Studying the Prevalence of Gestational Diabetes Mellitus in Indian Pregnant Women Along with Efficacy and Type of Treatment Provided to Control the Diabetes

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### ABSTRACT

Pregnancy is a diabetogenic condition due to progressive increase in the insulin resistance. The diabetogenic effects of pregnancy are due to Insulin resistance since there is production of anti-insulin hormones like human placental lactogen, cortisol, estriol and progesterone. Also due to increased destruction of insulin by kidney and placenta (insulinase). Gestational Diabetes Mellitus occurs when there is insufficient insulin secretion to counteract the pregnancy-related decrease in insulin sensitivity. The study was conducted at a tertiary care hospital where 500 pregnant were enrolled for the study. All pregnant women (<24wks) who register for first time were screened by fasting blood sugar levels for Gestational Diabetes Mellitus. Those with normal fasting sugars were further evaluated by glucose tolerance test at 24-28 weeks. Patients with abnormal levels were identified and referred to Endocrinology Department of Medical College Hospital for further treatment. One hundred three (21%) were diagnosed as Gestational Diabetes Mellitus, thus the prevalence was 21.0% as per IADPSG Criteria. Considering the DIPSI Criteria the prevalence of Gestational Diabetes Mellitus would have been 27 (5.4%). 97(92.4%) had glycaemic control on Medical Nutrition Therapy and Life-Style Modifications, 8 patients required Insulin therapy. It is feasible to perform the screening for Gestational Diabetes Mellitus by the IADPSG. Elderly participants, with high BMI are at high risk for Gestational Diabetes Mellitus.

## INTRODUCTION

Gestational Diabetes Mellitus occurs when there is insufficient insulin secretion to counteract the pregnancy-related decrease in insulin sensitivity. During pregnancy, as gestation progresses, postprandial glucose levels steadily increase as insulin sensitivity steadily decreases. For glucose control to be maintained in pregnancy, it is necessary for maternal insulin secretion to increase sufficiently to counteract the fall in insulin sensitivity. In Gestational Diabetes Mellitus, HbA1c is insufficiently sensitive to substitute for Oral Glucose Tolerance Test as a screening test. The extended effect of previous glycaemia limits the utility of HbA1c in pregnancy, where the goals of rapid improvements in glucose control demand direct glucose monitoring<sup>[1-2]</sup>. The original method of screening for Gestational Diabetes Mellitus was dependant on personal history and family history<sup>[3]</sup>. In the Indian context, screening is essential in all pregnant, as the Indian women have 11 fold increased risk of developing glucose intolerance during pregnancy compared to Caucasian women<sup>[4]</sup>. O'Sullivan et al. evaluated a 50gm, 1 hour Glucose Challenge Test to screen for Gestational Diabetes Mellitus<sup>[5]</sup>. Those pregnant women who were screened positive by Glucose Challenge Test are further tested by Oral Glucose Tolerance Test with 100 gm glucose. The test is performed in the morning after an overnight fast for at least 8 hours but not more than 14 hours and after at least 3 days of unrestricted diet (150 g carbohydrate) and physical activity. Subsequent information has led to alteration in O'Sullivan's criteria. For example, there is growing evidence that one value is sufficient to make an impact on the health of the fetus and is now the criterion used by most clinicians to initiate treatment. Whole blood glucose values are lower by 14% than plasma levels due to glucose uptake by haemoglobin. The present values used by the American College of Obstetricians and Gynecologists are based on a theoretical increase in haemoglobin and plasma with pregnancy<sup>[5]</sup>.

The Diabetes in Pregnancy Study group India (DIPSI) has recommended practice guidelines for Gestational Diabetes Mellitus in the Indian environment. To standardize the diagnosis of Gestational Diabetes Mellitus the World Health Organisation (WHO) proposed using a 2 hour 75 gms Oral Glucose Tolerance Test with a threshold plasma glucose concentration of greater than 140 mg dL<sup>-1</sup> at 2 hour, similar to that of Impaired Glucose Tolerance (IGT), outside pregnancy. All these recommendations (DIPSI and WHO) have not projected the influence of the glycaemic level on fetal outcome<sup>[6]</sup>. With newer diagnostic threshold the prevalence of Gestational Diabetes Mellitus in the general obstetric population may be upto 18%<sup>[7]</sup>. Today most Diabetic Associations recommend Universal screening for non-Caucasian

population because of beneficial effects from screening, diagnosis and subsequent treatment. The non-pharmacological treatment consist of medical nutrition therapy and life style modification done to achieve normoglycemia, prevent ketosis, provide adequate weight gain in Gestational Diabetes Mellitus mothers and to contribute fetal well-being. The dietary recommendations to the Gestational Diabetes Mellitus patients should depend upon the nutritional components caloric allotment, carbohydrate intake and caloric distribution. Thus a personalized nutritional plan based on individual's body mass index should be made by a registered dietician. A light exercise done after eating has been shown to reduce post-prandial blood glucose<sup>[8]</sup>. Insulin has been the gold standard in the treatment of Gestational Diabetes Mellitus most of the endocrinologists the use of short acting insulin (onset of action 30 min. lasting for 6-8 hours) and intermediate acting NPH insulin (onset action of 1 hour, lasting for 11 to 14 hours). The requirement of insulin increases with gestational age, obesity, glycaemic control and other factor. Those of insulin varies from 0.6-1U kg<sup>-1</sup> day in divided doses depending on the trimester of pregnancy. Insulin is recommended those who are not able to achieve the glycaemic targets with Medical Nutrition Therapy. The use of oral hypoglycaemic agents has been used by many obstetricians and endocrinologists in clinical practice. Metformin and Glyburide were the most frequently studied drugs. There are many studies on the prevalence of Gestational Diabetes Mellitus in our population and the role of Oral Glucose Tolerance Test in diagnosis of Gestational Diabetes Mellitus. However, there is no study in Indian population for diagnosis of Gestational Diabetes Mellitus using the newer criteria for cut off as put forth by the International Association of Diabetes in Pregnancy and Study Group (IADPSG). Therefore, the above study was conducted to study the prevalence of Gestational Diabetes Mellitus in Indian pregnant women along with efficacy and type of treatment provided to control the diabetes.

## MATERIALS AND METHODS

**Study Place:** The study was conducted at a tertiary care hospital for period of 1 year.

**Study Design:** Retrospective observational study.

**Inclusion Criteria:** All pregnant women (<24wks) who register for first time and ready to give consent were screened by fasting blood sugar levels for Gestational Diabetes Mellitus.

**Exclusion Criteria:** Patients with pre-gestational diabetes and those who were not ready to give written consent.

**Sample Size:** 500 Indian pregnant women.

**Data Analysis:** All the data was analysed, recorded and entered in the form of tables through Microsoft SPSS 22 version. Kappa Test used for comparison of IADPSG and DIPSI criteria.

**Ethical Consideration:** The Institutional Ethics Committee permission was obtained for conducting the study. All the pregnant women enrolled for the study were screened and evaluated for Gestational Diabetes Mellitus by doing Oral Glucose Tolerance Test. Thresholds of blood glucose values of Oral Glucose Tolerance Test as per the IADPSG criteria were as follows:

Blood sugar levels

- Fasting blood sugar =92mg dL<sup>-1</sup>
- 1 hour =180mg dL<sup>-1</sup>
- 2 hour =153mg dL<sup>-1</sup>

If the Oral Glucose Tolerance Test is abnormal that is even if single value is deranged, these patients are labelled as Gestational Diabetes Mellitus. Treatment regarding glycaemic control was given as per advice of Endocrinology Department. In addition, all patients diagnosed with Gestational Diabetes Mellitus by above criteria were Hba1c done, to assess glycaemic levels of last 3 months. Such patients were subsequently referred to Endocrinology department. Their advice regarding Medical Nutrition Therapy and Lifestyle modifications was done. All patients were made to monitor their sugar levels by commercially available Glucometer, firstly 6 times a day and subsequently less frequently depending on the glycaemic controls. Fasting value should be <95mg dL<sup>-1</sup> and post-prandial 2 hour should be <120 mg dL<sup>-1</sup>. Patients were assessed after one week, if the glycaemic control is normal, then they do continue Medical Nutrition Therapy and lifestyle modifications and if the glycaemic control is not achieved then Insulin therapy is added on as per Endocrinologist advice.

## RESULTS

Total 500 participants were screened by Oral Glucose Tolerance Test (Oral Glucose Tolerance Test), 105 participants were found to have Gestational Diabetes Mellitus, hence prevalence of Gestational Diabetes Mellitus is 21.0% as per IADPSG Criteria. If the DIPSI criteria were applied to the total 500 participants were screened by Oral Glucose Tolerance Test, 27 participants were found to have Gestational Diabetes Mellitus as per DIPSI Criteria (2 hour value >140 mg dL<sup>-1</sup>), hence prevalence of Gestational Diabetes Mellitus by DIPSI criteria would have been 5.4%.

When both the tests were compared it was shown that there was overall agreement in 82.4% of cases with simple kappa value 0.271 (Fair agreement), for a diagnosis of Gestational Diabetes Mellitus this is statistically significant (p<0.001).

In the above table, total 500 patients were screened by Oral Glucose Tolerance Test, 105(21%) diagnosed as Gestational Diabetes Mellitus by IADPSG Criteria whereas 27(5.4%) by DIPSI Criteria. Twenty two patients were Gestational Diabetes Mellitus according to both the criteria and 390 were Non-Gestational Diabetes Mellitus according to both hence there is fair agreement by Kappa (82.4%) 5 patients were Gestational Diabetes Mellitus as per DIPSI Criteria which are Non-Gestational Diabetes Mellitus as per IADPSG Criteria. Eighty three patients would have been missed by DIPSI Criteria if this was the basis of diagnosis of Gestational Diabetes Mellitus.

Out of 105 Gestational Diabetes Mellitus participants, 97 participants (92.3%) were controlled on diet however 8 participants (7.8%) failed to control on Medical Nutrition Therapy and Life-style modification thus the Insulin therapy was added on.

There were total 19 elderly (= 35Years) of which 8 (42.1%) were diagnosed with Gestational Diabetes Mellitus 11 (57.9%) were not having Gestational Diabetes Mellitus. Hence, there was a positive co-relation of advanced maternal age with Gestational Diabetes Mellitus. The incidence of Gestational Diabetes Mellitus in different BMI groups at first registration, is 66.7% and there is a co-relation of high BMI (>30kg cm<sup>-2</sup>) and Gestational Diabetes Mellitus, 0% in low BMI, and 33.3% in normal BMI. This is significant in our study.

## DISCUSSIONS

Many studies suggests that the prevalence of Gestational Diabetes Mellitus is higher in non-Caucasian population (ref Clinical Diabetes April 2013 vol. 31 no. 2 90-94?). The prevalence of Gestational Diabetes Mellitus in above study was 21.0% using the IADPSG criteria. In a study conducted by Novak *et al.*<sup>[9]</sup> at Pondicherry Institute of Medical Sciences, 304 pregnant women were screened by using the same Criteria the prevalence of Gestational Diabetes Mellitus was 27% (83/304), which is comparable to our study.

Balaji *et al.*<sup>[10]</sup> conducted at Government Maternity Hospital, Chennai, India 891 women were screened by 75gm Oral Glucose Tolerance Test as per World Health Organisation criteria the prevalence of Gestational Diabetes Mellitus was 18.9% which is also comparable to our study. In a study done by Rajesh *et al.*<sup>[11]</sup> at Post Graduate Institute of Medical Sciences (PGIMS)

Table 1: Prevalence of gestational diabetes mellitus in study group (As per IADPSG Criteria)

Number of participants screened	Number of patients with gestational diabetes mellitus	Percentage
500	105	21.0

Table 2: Prevalence of gestational diabetes mellitus (as per DIPSI criteria) (n=27)

Number of person Screened	Number of patients with gestational diabetes mellitus	Percentage
500	27	5.4

Table 3: Comparison of gestational diabetes mellitus as per IADPSG and DIPSI criteria in the study group

DIPSI	IADPSG		Total
	Yes	No	
Yes	22 (21.0%)	5 (1.3%)	27 (5.4%)
No	83 (79.0%)	390 (98.7%)	473 (94.6%)
Total	105 (100%)	395 (100%)	500 (100%)

Table 4: Treatment given in gestational diabetes mellitus group

Mode of treatment	Medical nutrition therapy + life style modification	Medical nutrition therapy + life style modification + insulin	Total
Number of patients on treatment	97 (92.4)	08 (7.6)	105 (100)

Table 5: Co-relation of advanced maternal age with gestational diabetes mellitus in our study group

Elderly gravida (>35 years)	Gestational diabetes mellitus		Total
	Yes	No	
Yes	8 (42.1)	11(57.9)	19 (100)
No	97 (20.2)	384 (79.8)	481 (100)
Total	105 (21.0)	395(79.0)	500 (100)

Pearson  $\chi^2$  value = 5.3, df =1, p = 0.021 (Significant)

Table 6: Incidence of gestational diabetes mellitus in different body mass index (BMI ) groups at first registration (n-105)

Body mass Index (kg m <sup>-2</sup> )	Gestational diabetes mellitus		Total
	Yes	No	
High(>30)	12 (66.7%)	6 (33.3%)	18(3.6%)
Low(<19)	0 (0.0%)	9 (100.0%)	9(1.8%)
Normal (19- 29.9)	93 (19.7%)	380 (80.3%)	473(94.6%)
Total	105 (21.0%)	395 (79.0%)	500

Pearson  $\chi^2$  value = 25.53, df = 2, p<0.001 (Significant)

Haryana was 7.1% by ADA criteria and Rajasthan 6.6% by DIPSI criteria, which is low and not consistent with above study.

One more study undertaken in Kanchipuram District of Tamil Nadu, total 1031 pregnant women were screened by both fasting and non-fasting Oral Glucose Tolerance Test. In this study the prevalence of Gestational Diabetes Mellitus by DIPSI Criteria is 23 (2.23%), by WHO 83 (8.0%), by IADPSG Criteria 106 (10.28%), thus DIPSI had low sensitivity as compared to WHO and IADPSG Criteria<sup>[12]</sup>. Compared with Non-Gestational Diabetes Mellitus, Gestational Diabetes Mellitus patients were older. A study from south India showed age >25 years as a risk factor for Gestational Diabetes Mellitus<sup>[13]</sup>.

Several studies had supported that Obesity is a significant risk factor for Gestational Diabetes Mellitus, overweight or Obesity at the start of pregnancy predisposes to Gestational Diabetes Mellitus. In above study, 66.6% were obese participants having Gestational Diabetes Mellitus, which was 67% in Priyanka *et al.*<sup>[14]</sup> and 27.5% in Wahi *et al.*<sup>[15]</sup>, it is also high in other studies like Das *et al.*<sup>[16]</sup> (25%), Gomez *et al.*<sup>[17]</sup> Nilofer<sup>[18]</sup> found obesity as a risk factor in 88.89% of Gestational Diabetes Mellitus patients.

## CONCLUSION

The prevalence of Gestational Diabetes Mellitus in above study population was (21%). It is necessary to offer universal screening for Gestational Diabetes

Mellitus. It is feasible to perform the screening for Gestational Diabetes Mellitus by the IADPSG. We found that the Elderly participants, with high BMI are at high risk for Gestational Diabetes Mellitus.

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