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COMPARISON OF SCREENING OF GESTATIONAL DIABETES MELLITUS USING DIPSI (DIABETES IN PREGNANCY STUDY GROUP INDIA) GUIDELINES WITH SCREENING USING ORAL GLUCOSE TOLERANCE TEST

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ABSTRACT

BACKGROUND: Diabetes mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. Gestational Diabetes Mellitus refers to carbohydrate intolerance of varying severity with onset or first recognition during pregnancy, regardless of persistence after delivery. GDM leaves the pregnant mother, as well as her child, at risk of developing chronic diabetes. There is also increased incidence of macrosomia, caesarean sections, shoulder dystocia and birth trauma. Prevalence of GDM can be as high as 14% in high-risk ethnic groups. In the Indian context, Indian women have 11-fold increased risk of developing GDM compared to Caucasian women. Thus, universal screening of GDM, rather than risk factor screening, is a public health priority.

To diagnose GDM, WHO recommends a 2-hour 75-gram OGTT to be conducted after overnight fasting, with a threshold plasma glucose concentration of greater than 7.8 mmol/L. Diabetes in Pregnancy Study Group India (DIPSI) diagnostic criterion is a modified version, and is performed in the feasting/non-fasting state.

This study aimed to ascertain the validity of DIPSI criterion to diagnose GDM in Indian population.

METHODOLOGY: This prospective observational study included 370 pregnant women, between 24-28 weeks of gestation. Women with overt/pre-gestational diabetes were excluded.

The subjects underwent 75-gram OGTT in non-fasting state, in accordance with DIPSI guidelines. After a gap of 3-7 days, OGTT was performed after overnight fasting, according to WHO guidelines.

Results obtained from both tests were compared using Sensitivity, Specificity and Pearson's Correlation Coefficient.

RESULTS: The overall prevalence of GDM was 11.18%, and 11.36% in the high-risk group.

42 of the total participants i.e., 11.18% had 2-hour blood sugar values greater than 140 mg/dl after undergoing OGTT in non-fasting state. On undergoing OGTT in fasting state, 42 i.e., 11.18% were seen to have 2-hour blood sugar values greater than 140 mg/dl. The values obtained from both tests thus showed a positive correlation, indicating that an increase in 2-hour blood glucose values after ingestion of 75-gram glucose in non-fasting state, was associated with a similar increase when performed in fasting state. Sensitivity of DIPSI method was calculated as 98.01% and specificity of DIPSI method was calculated as 98.31%.

CONCLUSION: This study supports the concept of universal screening and the use of 75-gram OGTT with a cut-off value of 140 mg/dl, irrespective of the last meal timing, as a good screening method due to the high sensitivity and specificity obtained in our study.

KEYWORDS

Gestational Diabetes Mellitus, Screening, DIPSI

INTRODUCTION

Diabetes mellitus refers to a group of metabolic disorders that share the phenotype of hyperglycemia[1]. Gestational Diabetes Mellitus or GDM is characterized by carbohydrate intolerance of varying severity with onset or first recognition during pregnancy[2], regardless of the need for insulin or persistence of the diabetic state after delivery[3,4].

During pregnancy, metabolism adapts according to maternal requirements, and to provide fuel for the feto-placental unit. During the latter half of pregnancy, an increase in glucose levels is seen due to an increase in placental hormones like Human Placental Lactogen, Cortisone, Human Growth Hormone and Prolactin. The maternal metabolic adaptation to maintain the mean fasting plasma glucose of 74.5±11 mg/dl and the postprandial peak of 108.7±16.9mg/dl is possible due to compensatory hyperinsulinemia. A pregnant woman who is unable to increase her insulin secretion thus develops Gestational Diabetes Mellitus.

GDM is a fast-growing problem, with an increase in prevalence in all races and ethnicities[5]. Although there is a reported prevalence between 2-5%, it can be as high as 14% in high risk groups[3,4]. In the Indian context, Indian women have 11-fold increased risk of developing glucose intolerance during pregnancy compared to Caucasian women[6].

The importance of GDM is that two generations are at risk of developing diabetes in the future, the pregnant mother, as well as her child[7,8,9]. There is also an increased incidence of macrosomis[10,11], and an associated increase in birth trauma, shoulder dystocia and caesarean section[12]. This, along with the increasing prevalence of GDM, especially in ethnic populations[13,14,15,16,17,18,19,20], shows the importance of universal screening and care of GDM, making it a public health priority[21].

Indian Guidelines

The WHO endorses universal screening, at 24-28 weeks of pregnancy, using the 75-gram oral glucose tolerance test (OGTT)[22]. 75-gram anhydrous glucose is administered orally in 250-300 ml water, after overnight (8-14 hours) fasting. Pregnant women with 1 or more positive values are classified as having GDM.

Fasting ≥ 126 mg/dL
2 hours ≥140 mg/dL

Disadvantages:

- Owing to commuting difficulties, as well as social beliefs against prolonged fasting in pregnancy, it is highly unlikely that a pregnant woman would come for an antenatal visit in fasting state, with a high dropout rate should she be asked to come in fasting state in subsequent visits[23].
- Ethnically, Asian Indians have high insulin resistance due to which their 2-hour Plasma Glucose is high as compared to Caucasians[24]. The insulin resistance during pregnancy escalates further[25]. Hence, Fasting Plasma Glucose is not an appropriate option to diagnose GDM in this population.

Thus, it was important to develop a test that detected glucose intolerance without the woman necessarily undergoing a test in the fasting state, in order to make universal screening during pregnancy economical and feasible[26,27].

DIPSI Recommended Method

In the antenatal clinic, a pregnant woman is given a 75-gram oral glucose load, regardless of her last meal[28]. A venous blood sample is collected at 2 hours and GDM is diagnosed if 2-hour Plasma Glucose ≥ 140 mg/dL. This is done between 24-28 weeks of gestation[28].

Rationale: After a meal, a normal glucose tolerant woman would be able to maintain euglycemia despite glucose load due to brisk and adequate insulin response. A woman with GDM however, has impaired insulin secretion,[27] and her glycemic level increases with a meal, further exaggerated with the glucose load.[29] Thus, the occurrence of false positives is highly unlikely.

Advantages of the DIPSI procedure:

- Fasting state not required[30]
- Minimum disturbance to pregnant woman's routine
- Screening as well as diagnostic procedure

This single-step procedure has been approved by Ministry of Health, Government of India[31].

METHODOLOGY

A prospective observational study was conducted in the Department of Obstetrics and Gynecology, Central Referral Hospital – SMIMS, Gangtok, for a period of 18 months from January 2015 to June 2016. A total of 370 pregnant women at 24-28 weeks of gestation were included in this study. Women with overt diabetes were excluded. The data was collected from patients with the help of a study proforma on interview basis after obtaining consent. Detailed history was elicited and clinical examination was done.

All the participants underwent the 75-gram OGTT in non-fasting state, in accordance with DIPSI guidelines. Non-fasting venous sample was drawn, following which, the participants ingested 75-gram of glucose dissolved in 200 ml of water over a five-minute period, regardless of her last meal. After 2 hours, venous sample was obtained. Plasma glucose was measured in both samples, and the values were noted in the study proforma.

Following this, the participants were asked to review in OBG OPD after a gap of 3-7 days, in a state of overnight (8-14 hours) fasting. At this point, OGTT was performed. Fasting venous sample was drawn, following which, the participants ingested 75-gram of anhydrous glucose dissolved in 200ml of water over 5 minutes. After 2 hours, venous blood was obtained. Plasma glucose was assessed in both samples, and the values were noted in the study proforma.

RESULTS

192 of the total 370 participants belonged to high-risk group. Of those, 41.8% were more than 30 years of age, and 6.47% had family history of Diabetes Mellitus. 1.8 % had a history of recurrent pregnancy loss, with 1.8% having a history of IUD in prior pregnancies. 4.1% had a history of big baby (birth weight > 3.5kg), 1.2% gave history of anomalous baby, and 0.6% had a documented history of GDM in their prior pregnancies. 0.6% gave history of prior difficult delivery. 5.3% had associated hypertension or pre-eclampsia in the present pregnancy.

42 of the total participants were diagnosed with GDM and disease prevalence was calculated as 11.18%. The prevalence was 11.36% in high-risk group.

Maximum prevalence of 36.36% was seen in patients with family history of Diabetes Mellitus, and 33.3% was seen in patients with history of recurrent pregnancy loss. Prevalence was 33.3% in patients with associated hypertension or pre-eclampsia. A prevalence of 22% was seen in those with history of anomalous baby in prior pregnancies, and 14.29% in those with history of big baby in prior pregnancies.

The mean of the 2-hour plasma glucose values in fasting state (WHO guidelines) was 101.3 mg/dl. The mean in non-fasting state (DIPSI guidelines) was 108.3 mg/dl.

The standard deviation of the 2-hour plasma glucose in fasting state (WHO guidelines) was 20.29. The standard deviation in non-fasting state (DIPSI guidelines) was 19.51.

The values showed a Pearson product-moment correlation coefficient of 0.845, which lies between 0 and 1. Thus, the values show Positive Correlation, indicating that rise in the value of 2-hour blood glucose in non-fasting state, is accompanied by an increase in the corresponding value in fasting state.

On plotting all the values of 2-hour blood sugar in non-fasting as well as fasting state, according to the serial number of the patient, the following scatter plot (Figure 1) was obtained, which shows a linear line representing positive correlation.

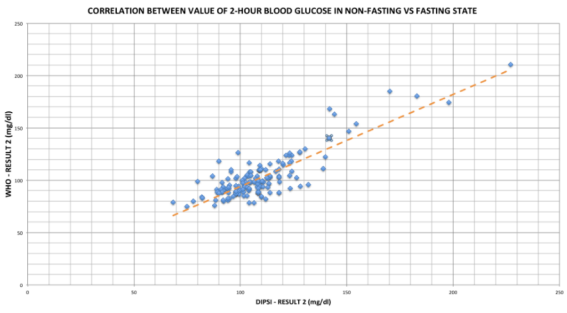

Figure 1

Sensitivity of DIPSI method was calculated as 98.01% and specificity of DIPSI method was calculated as 98.31%.

DISCUSSION

In this study, 370 pregnant women seeking antenatal care between 24-28 weeks of gestation who were willing to participate in the study were screened for GDM using Oral Glucose Tolerance Test (OGTT) done in Non-fasting state (DIPSI) and in Fasting state (WHO). The results obtained from both tests were compared with each other, with the aim of assessing the validity of DIPSI Criteria for the diagnosis of GDM.

Most women were between 21-35 years of age, with 40% belonging to the age group of 26-30 years. The predominant religion was Hinduism, with 71.8% Hindus. 155 participants were multigravida and 215 were primigravida.

Multiple risk factors were considered, and participants were classified as high risk or low risk. 51.8% belonged to high-risk group, i.e., they had one or more associated risk factors. Age, associated hypertension/pre-eclampsia, recurrent pregnancy loss, previous anomalous or big babies, and family history were seen as important risk factors.

Prevalence of GDM was calculated using OGTT in fasting state (WHO guidelines) as the diagnostic test. The prevalence of GDM in high-risk group in this study is 11.36% which was higher than the overall prevalence of 11.18%. Like earlier studies, incidence of GDM increases with increase in risk factors with maximum association seen in cases with history of recurrent pregnancy loss and with associated hypertension/pre-eclampsia.

On comparing results obtained from DIPSI method with those obtained from WHO method, no difference in results was seen. The values obtained while performing the two tests showed a positive correlation, indicating that an increase above normal in 2-hour blood glucose values after ingestion of 75-gram glucose in non-fasting state, was associated with a similar increase when done in fasting state.

The sensitivity of DIPSI method was calculated as 98.01%, whereas the specificity was calculated as 98.31%. On comparing OGTT when done in accordance with DIPSI guidelines vs WHO guidelines, the results obtained were shown to have a positive correlation.

CONCLUSION

Taking into consideration the increasing prevalence of GDM, India needs an economic and feasible screening method. Gestational diabetes mellitus can adversely affect maternal and fetal outcome. However early diagnosis of this disorder and its appropriate and timely management could significantly improve the outcome.

This study supports the concept of universal screening and the use of 75-gram OGTT with a cut-off value of 140 mg/dl, irrespective of the last meal timing, as a good screening method due to the high sensitivity and specificity obtained in our study.

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