

## STUDY OF EFFICACY OF 50 GRAMS ORAL GLUCOSE CHALLENGE TEST FOR SCREENING GESTATIONAL DIABETES MELLITUS IN PREGNANT WOMEN WITH NO RISK FACTORS

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### ABSTRACT

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#### BACKGROUND

Indian women are at high risk for Gestational Diabetes. Pregnancy complicated by Gestational Diabetes is associated with increased maternal as well as foetal morbidity. Early diagnosis and prompt management is essential.

#### METHODS

A prospective study was conducted at King George Hospital, Visakhapatnam, Andhra Pradesh, which is a tertiary care hospital. At 24-28 weeks period of gestation, 50 grams glucose dissolved in 300 mL water was given to patients irrespective of the fasting status. Blood glucose estimation was done after 1 hour by Glucose Oxidase-Peroxidase enzyme method. 140 mg/dL is taken as cut-off & those women positive for Glucose Challenge Test were further subjected to 100 grams Glucose tolerance test.

Women who were positive for Glucose Tolerance Test were diagnosed as having Gestational Diabetes and jointly managed by Obstetrician and Diabetologist. Pregnancy and neonatal outcomes were monitored.

#### RESULT

200 Antenatal women were taken into this prospective study. Glucose challenge test has high specificity of 97% and negative predictive value is 97%. Sensitivity of the test is 83% and positive predictive value is 83%. It can be effectively used as a screening test for Gestational Diabetes Mellitus.

#### CONCLUSION

Glucose Challenge Test is a highly specific test with a high negative predictive value. This test is economical, feasible and can be effectively used as a screening test for Gestational Diabetes.

#### KEYWORDS

Glucose Challenge Test, Gestational Diabetes Mellitus, Glucose Tolerance Test, Screening

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**INTRODUCTION:** Gestational Diabetes Mellitus is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. It is not only associated with increased incidence of maternal complications like preeclampsia, recurrent urinary tract infections, polyhydramnios, increased incidence of caesarean delivery, traumatic instrumental delivery, shoulder dystocia, postpartum haemorrhage, wound infection and sepsis but also with foetal complications like macrosomia, still births, sudden intrauterine foetal demise at term, foetal distress, birth injuries, neonatal hypoglycaemia, hypocalcaemia, polycythaemia, hyperbilirubinaemia, respiratory distress syndrome and increased neonatal intensive care unit admissions. There is also increased incidence of Type II Diabetes Mellitus in women with Gestational Diabetes.

Hence, screening for Gestational Diabetes is essential in countries like India where the burden of the disease is very high. Gestational Diabetic Women have 3-7 fold higher risk of developing type-II diabetes within 5-10 years. More than half of the women with Gestational diabetes ultimately develop overt diabetes in the ensuing 20 years.<sup>1</sup> Further recognition of glucose intolerance during pregnancy is more relevant in Indian context, as Indian women have 11-fold increased risk of developing Gestational Diabetes compared with Caucasian women. Hence, screening for Gestational Diabetes is very important, otherwise the pregnancy may end in foetal wastage. According to the analysis by the center for disease control and prevention, the prevalence of Gestational Diabetes is as high as 9.2%.

**AIM & OBJECTIVES:** The Aim of the study is to evaluate the efficacy of 50 grams oral glucose challenge test as a screening tool for diagnosing Gestational Diabetes in pregnant women with no risk factors. A prospective study was conducted at King George Hospital over a period of 18 months (Sep 2014 - Jan 2016).

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**METHODOLOGY:** A 50 grams oral glucose drink was given to the patient regardless of the previous meal followed by glucose estimation after 1 hour at 24 to 28 weeks of gestation. Venous Blood of 3 mL was collected with complete precautions in a sterile fluoride container and the samples were transported to the clinical laboratory at King George Hospital within 6 hours. Venous plasma glucose estimation was performed by Glucose oxidase-peroxidase enzyme method. Confirmatory testing with 100 gram Oral Glucose Tolerance Test was done on all subjects with screening test value more than or equal to 140 mg/dL. The threshold value of 140 mg/dL was taken as it increases the specificity of the test.

The diagnosis of Gestational Diabetes was confirmed by 100 grams Oral Glucose Tolerance Test. In Oral Glucose Tolerance Test, the patient was asked to take unrestricted diet for three days before the test. After an overnight fasting of at least 8 hours, venous plasma glucose was measured on 3 occasions i.e., fasting, 1 hour, 2 hours post prandial after giving a 100 grams glucose drink. The subject should remain seated and should not smoke throughout the test. The Carpenter and Coustan values as given below were considered in this study for the diagnosis of Gestational Diabetes.

- Fasting - 95 mg/dL
- 1 hour - 180 mg/dL
- 2 hours - 155 mg/dL
- 3 hours - 140 mg/dL

Two or more values must be met or for a positive result. All patients who were found to have Gestational Diabetes were referred to a dietician and jointly managed by an Endocrinologist and Obstetrician. Women whose sugar levels were well controlled on diet, pregnancy was allowed to progress to spontaneous labour but not past the dates, while for those women who required insulin therapy, pregnancy was terminated at 38 weeks. The outcome of pregnancies was assessed by studying the mode of delivery, maternal complications, operative interference and neonatal outcome.

**Inclusion Criteria:** All Antenatal women who were registered with age less than 30 years and who were having no risk factors for Gestational Diabetes were screened at 24-28 weeks of Gestational age.

**Exclusion Criteria:**

- Patients with known diabetes prior to conception.
- Women over the age of 30 years.
- BMI ≥ 30.
- Previous history of Glucose intolerance.
- Previous history of Macrosomia.
- Diabetes in first degree relative.
- History of unexplained Intrauterine Demise at term, still birth.
- Patients with other medical disorders affecting the perinatal outcome like renal disease, Heart disease and Chronic Hypertension.

**OBSERVATION AND RESULTS:** Out of 200 Antenatal women tested with Glucose Challenge Test, 12 (6%) were positive for Glucose Challenge Test and further subjected to 100 grams Glucose Tolerance Test and 10 (83%) of them developed Gestational Diabetes. Out of 188 (94%) women who were negative for Glucose Challenge Test, 2 (1.1%) developed Gestational Diabetes. 50% of Gestational Diabetes cases and 23% of Non-gestational Diabetes cases were delivered by caesarean section. Neonatal Intensive Care Unit admissions were in 66% of neonates born to Gestational Diabetes and 5% neonates of Non-gestational Diabetes. Glucose Challenge Test has a specificity of 97% with a sensitivity of 83%. Its Positive predictive value is 83% and negative predictive value is 97%.

Age	No. of Subjects
< 21 Years	50
21-25	128
26-29	22
<b>Total</b>	<b>200</b>

**Table 1: Analysis of Results with Reference to Age**

Most of the women in this study were in the age group of 21-25 years.

GCT	GDM
Positive (12)	10 (83%)
Negative (188)	2 (1.1%)

**Table 2: Incidence of Gestational Diabetes in Women with positive Glucose Challenge Test**

83% of women who were positive for Glucose Challenge Test developed Gestational Diabetes.

Made of Delivery	GDM	NON GDM
Normal Labour	6 (50%)	146 (77%)
Caesarean Section	6 (50%)	42 (23%)

**Table 3: Analysis of Results With Reference to Maternal Outcome**

50% of cases of Gestational Diabetes were delivered by caesarean section, 23% of Non-gestational Diabetes cases by caesarean section. The indications for caesarean section were foetal distress (50%), cephalopelvic disproportion (33%) and malpresentations (17%).

	GDM	NON GDM
Total	12	188
Alive	12 (100%)	187 (99%)
IUD	0	1 (0.5%)
Still Birth	0	0

**Table 4: Analysis of Results with Reference to Foetal Outcome**

66% of neonates born to Gestational Diabetic mothers were admitted in Neonatal Intensive Care Unit compared to 5% of neonates born to non-gestational diabetic mothers. No Intrauterine Demises or still births were reported in the Gestational Diabetes group.

Sensitivity	83%
Specificity	97%
Positive Predictive Value	83%
Negative Predictive Value	97%
<b>Table 5: Validity of the Test</b>	

Glucose Challenge Test has high specificity and negative predictive value of 97%.

**DISCUSSION:** Pregnancy is associated with profound changes in the fat and carbohydrate metabolism. The placenta, anterior pituitary and adrenal cortex all play an important role in the endocrine adaptation of pregnancy. In normal pregnancy, glucose metabolism is characterised by a lower fasting plasma and elevated postprandial values. These changes occur as early as 10 weeks. In the first few weeks of pregnancy, maternal carbohydrate metabolism is affected by a rise in maternal levels of oestrogen and progesterone, which stimulate pancreatic beta cells, causing hyperplasia of the cells and increase in insulin secretion. At the same time, there is an increase in the tissue storage of glycogen, decrease in the production of hepatic glucose, and increase in peripheral utilisation of glucose and a decrease in maternal fasting levels of plasma glucose. The overall metabolic effect is anabolic. During the latter half of pregnancy, carbohydrate metabolism is stressed by the rising levels of human placental lactogen, prolactin, cortisol and glucagons. These hormones cause decreased glucose tolerance, insulin resistance, decreased stores of hepatic glycogen and an increase in production of hepatic glucose.

On a cellular level, increased binding of insulin to adipocytes and hepatocytes causes insulin resistance due to a post-receptor mechanism. This physiologic effect is to ensure a constant supply of glucose, lipids and amino acids to the foetus. With the rise of human placental lactogen, a polypeptide hormone produced by syncytiotrophoblast in pregnancy, lipolysis is stimulated in adipose tissues, which causes release of glycerol, fatty acids, reducing both maternal glucose and amino acid utilisation, sparing the fuel for the foetus. Its actions are in part responsible for the diabetogenic state of pregnancy. With placental growth, large amounts of counter insulin factors are synthesized. Glucose is transported across the placenta by facilitated diffusion, with foetal glucose levels generally 10 to 20 mg/dL below those in the maternal circulation. Excess substrates may be transported to the foetus, resulting in foetal hyperinsulinaemia. Active transport of amino acids by the placenta results in maternal hypoaminoacidaemia. Ketones readily diffuse across the placenta, whereas free fatty acids are transferred in limited amounts by gradient dependent diffusion. Foetal brain and liver oxidise ketones for foetal use.

Infants of diabetic mothers have higher endogenous insulin levels than do normal newborns, and these levels correlate with the presence of macrosomia. Hyperinsulinaemia combined with blunted glucagon response is responsible for the hypoglycaemia, commonly noted in neonates of diabetic mothers. Other neonatal problems include hypocalcaemia, polycythaemia and hyperbilirubinaemia. Hypocalcaemia has been attributed to transient functional neonatal hypoparathyroidism, although the exact mechanism is not known. The controversial issues in modern medicine need to resolve the question of who should be screened and what the cost of universal versus selective screening will be. As there is an increase in perinatal mortality in Gestational Diabetics, who were not identified or treated, as well as an increase in perinatal morbidity mainly macrosomia and its related complications, it is reasonable to assume that establishment of universal screening, early identification and proper treatment will result in lower overall cost as compared to the social and financial burden of poor perinatal outcomes due to undetected and untreated diabetes. One study found that if only high risk patients are screened, approximately 35% of Gestational Diabetes patients will not be discovered. The best screening method for Gestational Diabetes is the measurement of plasma glucose 1 hour after ingesting 50 grams of glucose as proposed by O Sullivan et al.

#### **The effects of diabetes on pregnancy include the following:**

- 1. Pre-eclampsia:** There is significant increase in incidence of preeclampsia in pregnant women with diabetes. The rate of preeclampsia increases with the severity of the diabetes.
- 2. Preterm Delivery:** Iatrogenic and spontaneous preterm delivery is increased in diabetic pregnancies, the reasons being poor glycaemic control, polyhydramnios, infection.
- 3. Polyhydramnios:** Polyhydramnios is often seen in diabetic pregnancies. Foetal polyuria that results from maternal and foetal hyperglycaemia has been suggested as a possible explanation.
- 4. Infections:** High incidence of chorioamnionitis and postpartum endometritis, urinary tract infections, candidal infections has been noted.
- 5. Postpartum Haemorrhage:** High incidence of postpartum haemorrhage is caused by exaggerated uterine distension as a result of macrosomia or polyhydramnios or both.
- 6. Caesarean Section:** There is a high incidence of caesarean section in pregnant diabetic patients.

#### **The neonatal complications include the following:**

1. Hypoglycaemia.
2. Hypocalcaemia.
3. Hypomagnesaemia.
4. Respiratory Distress Syndrome.
5. Hyperbilirubinaemia.
6. Hyper Viscosity Syndrome.

	<b>Present Study</b>	<b>O Sullivan</b>	<b>Carpenter</b>
GCT Threshold Value	140 mg/dL	130 mg/dL	135 mg/dL
GTT Criteria	95, 180, 155, 140	90, 165, 145, 125	95, 180, 155, 140
Gestational Age	24-28 wks.	24-28 wks.	24-28 wks.
Numbers Screened	200	752	381
GCT Positive	12	-	199
Test Specificity	97%	87%	76%

**Table 6**

The prevalence of Gestational Diabetes Mellitus in India is 16%. Since Gestational Diabetes is notorious for causing adverse effects in pregnancy and also foetal outcome, there is clear benefit by screening as it helps in early treatment.<sup>2</sup> Since the 50 grams glucose is easily be available for the Glucose Challenge Test and also can be performed on outpatient basis, it is easy, work friendly, cheap and convenient for screening purpose similar to study performed by Wong L and Tang ASA.<sup>3</sup> In 1973, O Sullivan et al proposed that a single sample of glucose tolerance performed without dietary preparation could provide an acceptable screening compromise. Hence, developed the concept about the 50 gram Glucose Challenge Test. In the present study, the cut-off taken is 140 mg/dL to increase the specificity of the test thereby reducing the number of false positives.

The criteria used for 100 grams Glucose Tolerance Test were Fasting – 95 mg/dL, 1<sup>st</sup> hour - 180, 2<sup>nd</sup> hour - 155, 3<sup>rd</sup> hour = 140 mg/dL similar to O Sullivan's study.<sup>4</sup> The screening test was performed at 24-28 wks. period of gestation as in Carpenter, O Sullivan studies.<sup>4,5</sup> Out of 200 women, Glucose Challenge Test was positive in 12 members (6%). It is 28% in Carpenter study. The disparity is due to the cut-off value taken (140 mg/dL in present study, 135 mg/dL in carpenter study). Cut-off value increased to minimise the number of false positives. Cousins favoured a cut-off of 130 mg/dL.<sup>6,7</sup> The specificity in this study was 97% which is comparable with O Sullivan (87%),<sup>4</sup> Carpenter (77%).<sup>5</sup> 12 out of 200 women tested positive were further subjected to Glucose Tolerance Test and 10 were diagnosed as having Gestational Diabetes.

2 out of 188 women with normal GCT developed GDM.

- 6 out of 12 cases (50%) of GDM were delivered by caesarean section.
- 3(25%) cases were complicated by preeclampsia 2 cases by postpartum haemorrhage (17%), abruption was seen in 8%. Our study is comparable to the study performed by Kim et al, Lindsay et al, Yogev et al.<sup>8,9</sup>
- 8 out of 12 neonates (75%) were admitted in NICU.
- No Intrauterine Deaths or still births reported.

**CONCLUSION:** Glucose Challenge Test has High sensitivity, Specificity, Negative predictive value. It is simple, convenient, cheap and easy to organise in Outpatient setting. It was well tolerated by all the patients.

Because of preventable adverse outcomes of both mother and foetus, it is worthwhile to perform for early detection of Gestational Diabetes by screening, hence can be used in countries like India, where the burden of Diabetes is high.

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