

## To Study First Trimester HbA1c As A Screening Test For Gestational Diabetes Mellitus

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### ABSTRACT

Pregnancy triggers several physiological changes to fulfil the escalating energy requirements of both the mother and the foetus. Insulin resistance significantly rises by 50-70% in both pregnancies without GDM and pregnancies with GDM. The HbA1c test now exhibits enhanced analytical stability due to increased standardisation between different assays and reduced variation in the pre analytical phase. Higher levels of maternal HbA1c are directly linked to a higher occurrence of adverse outcomes.

**Aim & Objectives:** To assess the validity of HbA1c as screening tool for Gestational Diabetes in the First Trimester Pregnancy.

To test the validity or sensitivity and specificity of first trimester **HbA1c screening** for Gestational diabetes in pregnant women attending the antenatal clinic.

**Materials And Methods:** A cohort of 100 pregnant women in first trimester attending the antenatal clinic in the department of Obstetrics and Gynecology in Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Salem were enrolled in a 17 months study. After getting approval from the institutional ethics committee, First-trimester pregnant women who satisfy the inclusion criteria will be employed for HbA1c testing along with FBS. Patients further will be evaluated with repeat HbA1c and 75gms 2hr DIPSI, followed by 75gms oral glucose tolerance test to confirm the diagnosis of GDM using WHO-2013 criteria in second and third trimester. These women will be followed till delivery to know the incidence of gestational diabetes and its effects on fetal maternal outcome. Statistical analysis as conducted using SPSS 23.0 software.

**Results:** The incidence of GDM in the present study was 46%. Among the 46 GDM participants, 9 exhibited a Negative OGCT result, while 37 showed a Positive OGCT result. GDM was associated with an increased frequency of both instrumental vaginal deliveries (3 versus 1) and cesarean sections (15 versus 5), with a statistically significant overall association observed ( $P = 0.005$ ). Statistical analysis produced P-values of 0.08, 0.81, and 0.40 for diabetic, non-diabetic, and prediabetic groups, respectively, highlighting varying associations between HbA1c levels and foetal outcomes in this cohort. NICU admission was necessary for 13% of the infants, while 87% did not require such admission.

**Conclusion:** HbA1c as a screening tool for gestational diabetes mellitus (GDM) during the first trimester appears promising, correlating significantly with subsequent OGCT results and maternal complications. The prevalence of GDM in the cohort was notable at 46%. The study underscores the effectiveness of early HbA1c testing in identifying at-risk pregnancies, emphasizing its potential role in enhancing prenatal care strategies and maternal-fetal health outcomes.

**Key Words:** GDM, HbA1C, First trimester Pregnant women, Oral Glucose Challenge test

## INTRODUCTION

Gestational diabetes mellitus (GDM) is the primary metabolic disorder in pregnancy, posing significant risks for mothers and infants. Glucose testing typically occurs between the 24th and 28th weeks of gestation in developed countries to detect GDM. However, differentiating it from pre-existing diabetes can be challenging due to limited pre-pregnancy screening. GDM accounts for about 90% of diabetes cases detected during pregnancy, affecting approximately 6-9% of pregnancies globally, with prevalence rates ranging from 1% to 14% influenced by diverse racial/ethnic backgrounds and varying screening and diagnostic criteria across regions.<sup>1,2</sup>

Universal glucose testing at 24-28 weeks' gestation is standard in most developed countries due to its increasing prevalence and the risk of adverse effects from high blood sugar during pregnancy.<sup>3</sup> The diabetogenic impact of pregnancy with advancing gestational age has delayed GDM screening and diagnosis until late in the second trimester or early in the third trimester. Previous studies suggest that women with GDM undergo metabolic changes early in pregnancy, indicating the possibility of earlier screening.<sup>4</sup>

GDM is distinguished by diminished functioning of the pancreatic  $\beta$ -cells. Women diagnosed with GDM experience heightened insulin resistance in their peripheral tissues, resulting in a 30-40% decrease in insulin sensitivity compared to women with normal glucose tolerance during pregnancy. Additionally, women with GDM experience reduced insulin production, hindering their ability to adequately compensate for insulin resistance, ultimately leading to hyperglycemia. The pronounced metabolic changes in GDM are attributed to factors such as autoimmunity, a predisposition for insulin resistance, or hereditary inheritance.<sup>5</sup>

Recent results from the hyperglycemia and poor pregnancy outcomes (HAPO) study show that HbA1c measurements strongly correlate with all negative outcomes, similar to glycemia levels. Higher maternal HbA1c levels are directly associated with increased adverse outcomes.<sup>6</sup> This study aims to assess HbA1c's role in detecting GDM in women receiving prenatal care.

## MATERIALS & METHODS

### *Study design and duration:*

This is a hospital-based prospective observational study that will evaluate the effectiveness of HbA1C as a screening tool over 18 months (December 2022 - June 2024) with a follow-up period of 6-9 months, i.e., till the delivery of the patient.

**Study Settings:** This study was conducted at the Vinayaka Mission's Kirupananda Variyar Medical College and Hospitals, Salem, Tamil Nadu, specifically at the Department of Obstetrics and Gynaecology.

### *SAMPLE SIZE CALCULATION:*

Prevalence of gestational diabetes: 3.8 to 20%

For 20% prevalence with formula  $4PQ/d^2$  (precision 10) the estimated sample is **62**.

Final sample of 70 is selected for the study.

### *STUDY POPULATION:*

Pregnant women in first trimester attending the antenatal clinic in the department of Obstetrics and Gynaecology in Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Salem.

### *INCLUSION CRITERIA*

- Pregnant women presenting at the antenatal clinic during the first trimester.
- Pregnant women providing informed written consent to participate in the study.

### *EXCLUSION CRITERIA*

- Pregnant women coming for the first antenatal visit after the first trimester.

- Pregnant women with overt diabetes mellitus.
- Pregnant women not willing to participate in the study by not giving written informed consent.

## METHODOLOGY

Step 1: Pregnant women attending the antenatal clinic will be enrolled in the study after receiving institutional ethics committee approval.

Step 2: First-trimester pregnant women meeting the inclusion criteria and providing written informed consent will be recruited.

Step 3: Detailed demographic data, including age, pre-pregnancy BMI, family history of diabetes, previous gestational diabetes mellitus, and PCOS, will be recorded during the initial visit.

Step 4: First-trimester HbA1c and fasting blood sugar (FBS) tests will be administered.

Step 5: Participants will then undergo repeat HbA1c testing and a 75g oral glucose challenge test (OGCT) using DIPSI criteria, followed by a 75g oral glucose tolerance test (OGTT) in the second and third trimesters to diagnose Gestational Diabetes Mellitus (GDM) per WHO-2013 criteria.

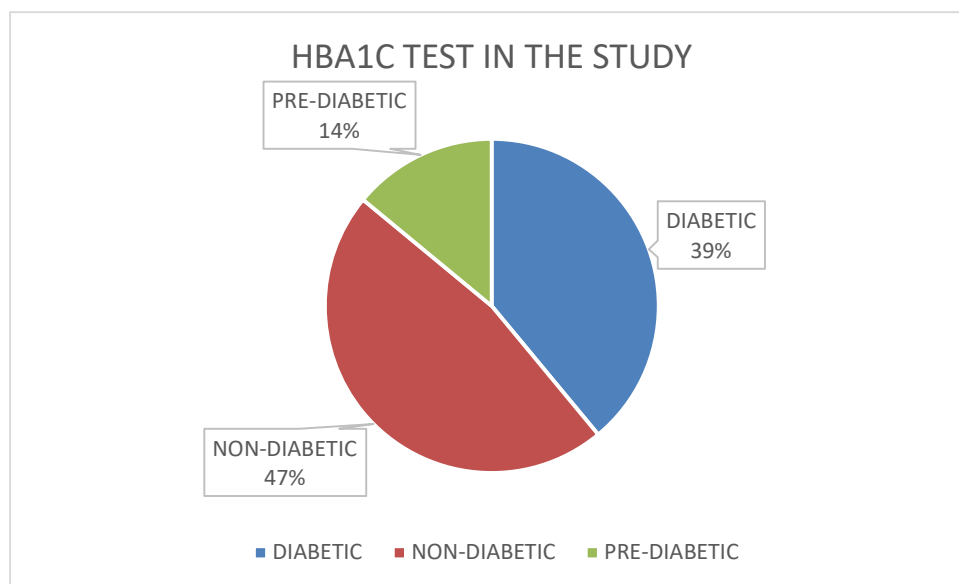
Step 6: Participants will be monitored until delivery to assess the incidence of gestational diabetes and its impact on maternal and fetal outcomes.

## STATISTICAL ANALYSIS:

- Data were entered into Excel and analyzed using IBM SPSS 23.0.
- Descriptive statistics, including percentage and frequency for discrete variables, and standard deviation, median, and mean for continuous variables, were used.
- Inferential statistics involved comparing discrete variables between groups using the Chi-square test or Fisher's exact test for categorical data. Continuous variables were compared using the Independent T test or the Mann-Whitney test, depending on normality assumptions.
- A significance threshold of 0.05 was applied to all tests.

## RESULTS

**Figure 1. HbA1C Screening in this Study**



HbA1c as a screening test in the first trimester, about 14% were pre-diabetic, 39% diabetic, and 47% were found to be non-

diabetic.

**Table 1. Family history of diabetes and GDM**

FAMILY HISTORY OF DIABETES MELLITUS	GESTATIONAL DIABETES		TOTAL
	GDM	NON GDM	
ABSENT	34	51	85
PRESENT	12	3	15
TOTAL	46	54	100
P VALUE 0.004			

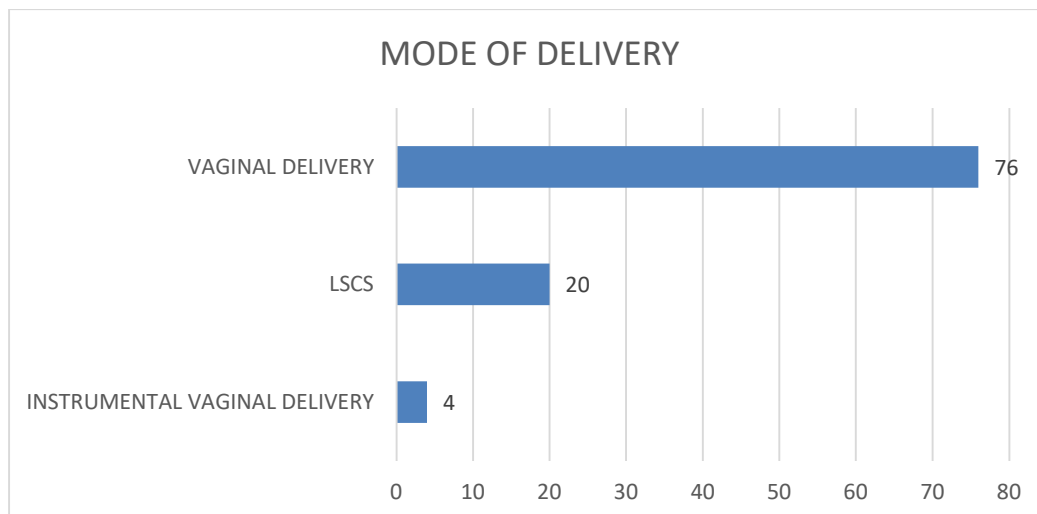
**Table 2. OGCT Test and Sample Distribution**

OGCT TEST	GDM	NON GDM	TOTAL
NEGATIVE	9	26	35
POSITIVE	37	28	65
TOTAL	46	54	100
P VALUE 0.03			

**TABLE 3. Association between gestational diabetes and HbA1c**

ASSOCIATION BETWEEN GESTATIONAL DIABETES AND HBA1C				
GESTATIONAL DIABETES	HBA1C			TOTAL
	DIABETIC	NON DIABETIC	PREDIABETIC	
GDM	22	15	9	46
NA	17	32	5	54
Total	39	47	14	100
P VALUE 0.025				

**Figure 2. Mode of Delivery**



## DISCUSSION

In India, where the prevalence of GDM is notably elevated, widespread screening is critical to mitigate potential adverse outcomes for both mother and child. The mean age of the patients in this study was  $20 \pm 13.8$  years. Most study participants (34%) were between 21 and 25 years old.

Ali S.<sup>7</sup> and the current study reported notably high rates of 73.9% and 80.4%, respectively, indicating a substantial proportion testing positive for glucose intolerance or gestational diabetes mellitus (GDM) in these cohorts. This underscores the critical need for effective screening protocols and management strategies in at-risk populations.

Within this study, 26% of the GDM cohort had a familial history of diabetes, highlighting a statistically significant association between pregnancy-related GDM and familial diabetes history ( $p = 0.004$ ). Retnakaran et al. (2007) investigated risk factors for gestational hyperglycemia, noting that while traditional GDM risk factors apply to women with a family history of diabetes (FHD), they may not be primary determinants for those without FHD. FHD emerged as a stronger GDM risk factor among nulliparous compared to parous women.<sup>8</sup>

In this study, 56.9% of patients tested positive early with OGCT, in contrast to earlier findings. Kushtagi et al. reported 29% with OGCT values  $\geq 140$  mg/dl before 20 weeks gestation, among whom 3.6% were later confirmed with GDM through follow-up OGTT.<sup>9</sup>

Using HbA1c as a first-trimester screening tool for GDM shows promise, correlating significantly with subsequent OGCT results and maternal complications. The study cohort exhibited a 46% prevalence of GDM, linked to a familial history of diabetes mellitus. Despite diverse socioeconomic backgrounds and BMI distributions, the study underscores the effectiveness of early HbA1c testing in identifying at-risk pregnancies, potentially enhancing prenatal care and maternal-fetal health outcomes. pregnancies, thereby potentially enhancing prenatal care and maternal-fetal health outcomes.

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