**Original research article**

# HbA1c as a Predictor in Early Diagnosis of Gestational Diabetes Mellitus

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**Abstract**

**Aim:** This study is aimed to determine the efficacy of HbA1c as a predictor in early diagnosis of GDM.

**Methods:** A Prospective observational study was conducted at Geetanjali Medical College and Hospital, Udaipur from January 2020 to June 2021 in 106 pregnant patients with high risk factor for GDM attending antenatal OPD in the first trimester. Fasting blood glucose, HbA1c and all routine investigation at first trimester were performed. Patients with FBS >92 mg/dl or HbA1c was <6.5% in the first trimester were further evaluated in the second trimester for repeat HbA1c and 75gm 2hr DIPSI. In patients with HbA1c <6.5% and DIPSI value between 140-200 mg/dl were further subjected to 75 gm oral glucose tolerance test to confirm the diagnosis of GDM using WHO-2013 criteria.

**Result:** 91 out of the 106 antenatal patients were diagnosed with GDM based on WHO 2013 criteria. Keeping the cut off 5.5% for HbA1c, sensitivity of 90%, specificity of 80%, negative predictive value of 90.9% and positive predictive value of 94.7% was calculated for the prediction of GDM. The area under the curve of HbA1c in early pregnancy to predict GDM was 0.84.

**Conclusion:** This study provides positive correlation between first trimester HbA1c >5.5%, second trimester DIPSI and OGTT positive cases.

**Keywords:** HbA1c, Gestational diabetes mellitus, Predictor, OGTT, Early diagnosis

## INTRODUCTION

Gestational diabetes mellitus is defined as glucose intolerance of any degree with onset or first recognition during pregnancy.[1]About 1%-14% of all pregnancies are complicated by DM and out of them 90% were GDM worldwide. Prevalence of GDM varies from 3.8% - 21% in different parts of India, depending upon the geographical condition and the diagnostic method used.[2] Prevalence of GDM in Indian population is steadily increasing from 2% in 1982,7.2% in 1991 to 16.5% in2002.[3]

GDM is associated with an increased risk of maternal and fetal complications. Maternal complication mainly are spontaneous abortions, infection, ketoacidosis, eclampsia, gestational hypertension, instrumental as well as operative delivery, post-partum haemorrhage, injuries and sepsis. Fetal complications include shoulder dystocia, hypoglycaemia, hyperbilirubinemia and respiratory distress.

MoHFW Government of India recommends universal screening policy.[4]Diabetes In Pregnancy Study group of India **(**DIPSI) is a single step test and best screening method for GDM. 75 gm glucose is dissolved in approximately 300 ml water irrespective of the last meal and completed within 10 minutes. The test has to be repeated the next day if vomiting occurs in 30 minutes of oral glucose. If blood sugar level is ≥140 mg/dl then it suggests GDM. Values between 120 and 139 mg/dl denote impaired gestational glucose tolerance.

Glycosylated HbA1c is formed in a non-enzymatic pathway by haemoglobin's normal exposure to high plasma levels of glucose.HbA1c is a beta-N-1-deoxyfructosyl component of haemoglobin. In the normal 120 days life span of RBC, glucose molecules react with haemoglobin, forming glycated haemoglobin.HbA1c level is a proportional to average blood glucose concentration over a period of 4 weeks to 3 months because once glycated haemoglobin is formed it remains the same till its lifespan. HbA1c is most useful for pre conceptional counselling and to predict fetal outcome. Its advantages are that it can be measured at any time of the day, better analytical stability, less biological variations due to stress or illness, high reproducibility, no need of fasting and it is more comfortable for pregnant women.

Fasting blood glucose (FBG) is used as a screening tool for GDM.[5] However, FBG requires fasting, and has a great variability and poor repeatability, hence it is not effective for the early screening of GDM. American Diabetes Association standards of medical care in diabetes included HbA1c ≥ 6.5%[6] as the other criteria for diagnosing diabetes. It needs a single, non-fasting blood sample and it is measured by high performance liquid chromatography or by immunoassay. If the glucose intolerance is identified in the first trimester, it will help in differentiating pre gestational diabetes from gestational diabetes mellitus. If the HbA1c level is >6% she is likely to be a pre-gestational diabetes

Potential complications of GDM can be prevented by early diagnosis of overt or early onset gestational diabetes and incorporating lifestyle modification with timely initiation of treatment.

Aim of the study is to determine the sensitivity, specificity, positive predictive value and negative predictive value of HbA1c test in early diagnosis for GDM.

## MATERIAL AND METHOD:

This was a prospective observational study carried out in Geetanjali Medical College with attached tertiary care hospital in Udaipur, India. After the approval of the institutional Ethics Committee, data collection was performed over a period from January 2020 to June 2021. The patients attending antenatal OPD or maternity ward in the first trimester with high risk factors for GDM were included in the study. Patients with history of GDM in previous pregnancy, family history of DM, history of prematurity, history of fetal loss or unexplained neonatal loss, history of previous intrauterine death, history of polycystic ovarian disease, history of anomalous baby in previous pregnancy were considered having high risk factors for GDM.

Antenatal women having history of chronic kidney disease, hemoglobin variant, anemia, cardiac and respiratory disease, HbA1c>6.5 and known case of diabetes mellitus were excluded from the study.

Venous blood of all antenatal women for fasting blood glucose, HbA1c and all routine investigation in first trimester with high risk factors was taken. If the FBS was >92 mg/dl or HbA1c was <6.5% in first trimester, these values were considered abnormal and these patients were further evaluated in second trimester for repeat HbA1c and 75 gm 2hr DIPSI as a single step procedure irrespective of the last meal. All the patients were given 75 gm anhydrous glucose in 250-300 ml of water and plasma glucose level was estimated after 2 hours. If the value is <140 mg/dl then it is labelled normal and if value >200 mg/dl then it is diagnosed as overt diabetes. Any value is between 140-200mg/dl is considered as impaired glucose intolerance. Patients with HbA1c <6.5% and DIPSI Value between 140-200 mg/dl were further subjected to 75gm oral glucose tolerance test to confirm the diagnosis of GDM. GDM was diagnosed usingWHO-2013 criteria.

A detailed clinical history was recorded and thorough physical examination was performed at the time of presentation with specific emphasis on the risk factor of GDM. All pregnant women received standard antenatal care and treatment for GDM was started only in confirmed cases. The birth weight, APGAR score, admission in NICU, metabolic derangements and congenital anomalies were also taken into account. After discharge the patients were called after a period of 6 weeks for follow up. Fasting blood glucose level was done to check for persistence of raised blood sugar.

Fasting blood sample, DIPSI Sample, OGTT samples were collected in plain or fluoride vial. Blood sugar levels were analyzed on Roche/Hitachicobasc311 system by hexokinase method. HbA1c sample was collected in EDTA vial and analyzed by TINIA (turbidimetric inhibition immunoassay) method. Statistical analysis, data analysis was done on the basis of inferential statistics in which use of proportion, mean standard deviation and non-parametric test such as chi-square test was applied. Microsoft excel 2018 version was used for the statistical analysis. Student's t test was used to find the statistical significance of the observation. P value was calculated by SPSS (Statistical Package for the Social Sciences). The difference will be considered significant if the p value will be <0.05 and highly significant if it will be<0.01. A receiver operating characteristics (ROC) curve was used to evaluate the diagnostic performance of HbA1c by Med Calc software 20.022 versions.

## RESULTS

Out of 106 patients, 4 (4.2%) patients were between 18-25 years, 34 (36%) patients were between 26-30 years and 68 (72.1%) patients were above 30 years. Mean age of participants in our study was 32.9±4.5 years. 76 (71.7%) patients were multigravida. About half of the study participants (53) were overweight & approximately 19 (17.9%) were obese.

Out of 106 antenatal women, 91(85.8%) participants developed GDM in second or third trimester. WHO 2013 criteria is used to confirm the diagnosis of GDM. Maximum number of OGTT positive patients has HbA1c levels between 5.4% to 6.1%. In this study mean value of HbA1c is 6±0.23 % in GDM positive mother.

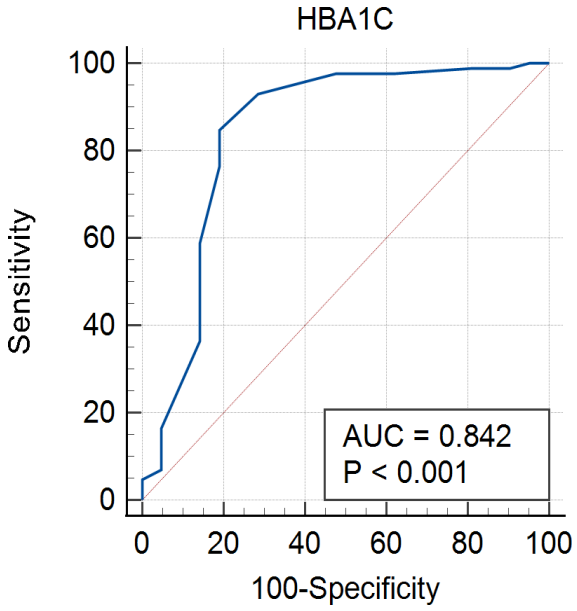
**Table 1: Baseline Characteristics of Participants**

| BASELINE CHARACTERISTICS | NUMBER OF PARTICIPANTS | % |
|---|---|---|
| **AGE GROUP** | | |
| 18-25 YEAR | 4 | 4.2 |
| 26-30 YEAR | 34 | 36.0 |
| >30 YEAR | 68 | 72.1 |
| **PARITY STATUS** | | |
| PRIMIGRAVIDA | 30 | 28.3 |
| MULTIGRAVIDA | 76 | 71.7 |
| **F/H/O DIABETES MELLITUS** | | |
| YES | 31 | 29.24 |
| NO | 75 | 70.75 |
| **BMI** | | |
| NORMAL | 34 | 32.1 |
| OVERWEIGHT | 53 | 50 |
| OBESE | 19 | 17.9 |
| **MODE OF DELIVERY** | | |
| FULL TERM FTND | 4 | 3.8 |
| PRETERM LSCS | 44 | 41.5 |
| FULL TERM LSCS | 58 | 54.7 |

**Table 2: Correlation of Different Levels HbA1c in First trimester & OGTT positive cases. (N=106)**

| HbA1c | 4.1-5 | 5.1-5.4 | 5.5-6 | 6.1-6.5 | TOTAL | Chi square | P VALUE |
|---|---|---|---|---|---|---|---|
| OGTT Positive | 1 | 8 | 71 | 11 | 91 | | |
| OGTT Negative | 2 | 10 | 2 | 1 | 15 | | |
| Total | 3 | 18 | 73 | 12 | 106 | 40.37 | 0.000008 |

**Table 2** shows correlation of different HbA1c levels & OGTT positive cases. It shows highly significant result at 95% level of significance as the value of HbA1c increases OGTT positivity also increases.




**GRAPH 1: ROC curve of first trimester HbA1c for diagnosis of GDM using OGTT (WHO 2013) diagnostic criteria as reference.**

The p-value and area under the curve between first trimester HbA1c and GDM is 0.001 and 0.842 respectively. This indicates that HbA1c can significantly diagnose GDM with high sensitivity and specificity.

**Table 3: Test Characteristics for HbA1c as a Predictor of GDM**

| HbA1c | SENSITIVITY | SPECIFICITY | PPV | NPV |
|---|---|---|---|---|
| 4.9 | 1 | 0 | 0.85849 | 0 |
| 5 | 1 | 0.06667 | 0.8666 | 1 |
| 5.1 | 0.989010989 | 0.13333 | 0.875 | 1 |
| 5.2 | 0.989010989 | 0.26667 | 0.89108 | 0.8 |
| 5.3 | 0.978021978 | 0.53333 | 0.909 | 0.8571 |
| 5.4 | 0.967032967 | 0.66667 | 0.91837 | 0.875 |
| 5.5 | 0.901098901 | 0.8 | 0.94737 | 0.909 |
| 5.6 | 0.824175824 | 0.93333 | 0.94737 | 0.909 |
| 5.7 | 0.747252747 | 0.93333 | 0.9565 | 0.7857 |
| 5.8 | 0.571428571 | 0.93333 | 0.9878 | 0.5833 |
| 5.9 | 0.362637363 | 0.93333 | 0.98571 | 0.3888 |
| 6 | 0.153846154 | 0.93333 | 0.9808 | 0.2593 |
| 6.1 | 0.120879121 | 0.93333 | 0.97436 | 0.20896 |
| 6.2 | 0.065934066 | 0.93333 | 0.96154 | 0.175 |
| 6.3 | 0.043956044 | 1 | 0.9444 | 0.15909 |
| 6.5 | 0.021978022 | 1 | 1 | 0.14285 |
| Mean HbA1c: 5.70±0.31 | | | | |

In our study at the cut off value of HbA1c of 5.5%, sensitivity is 90% without compromising specificity which is 80% to predict GDM with the area under the curve of 0.84. Its negative predictive value is 90.9% and positive predictive value is 94.7% for the prediction of GDM.
In our study, 31(29.3%) patients had family history of DM, 23(21.7%) patients had history of GDM in previous pregnancy and 24 (22.6%) patients had history of PCOD.
In our study 58 (54.7%) patients were managed by Medical nutrition therapy (MNT), 29 (27.4%) patients were managed by oral hypoglycemic drugs and insulin was used in 19 (17.9%) patients.
Most of the complications occur during antenatal period in our study. Out of 106 patients, polyhydramnios developed in 13 (12.2%) patients, PROM in 10 (12.2%) patients, IUGR in 8 (7.5%) patients, oligohydramnios in 6 (5.6%) patients, wound sepsis in 5 (4.7%) patients, anemia in 3 (2.8%) patients, APH, PPH & UTI in all 2 (1.8%) patients each, and post datism and shoulder dystocia in 1(0.9%) patient.
Maximum patients were delivered by LSCS in our study. 44 (41.5%) were delivered by pre-term LSCS, 58 (54.7%) by full-term LSCS and 4 (3.8%) were full-term vaginal delivery.
24 (22.2%) babies were admitted in NICU. Out of 108 babies, 12(11.2%) babies had hypoglycaemia, RDS in 7(6.4%) babies, neonatal jaundice in 3 (2.7%) babies and macrosomia in 2 (1.8%) babies. Mean birth weight of neonates in our study was 3.07 ± 0.49 kg.

**DISCUSSION:**

In our study out of 106 women, 91 patients develop GDM in their second and third trimester. Incidence was high because cases were selected having high risk factors for GDM.

Mean age of participants in index study was 32.9 ± 4.5years. 76(71.7%) patients were multigravida. Two cases were of twins in this study. There was no fetal loss or still birth reported in our study. Mean BMI of study participants was 23.01±1.7. In our study, 31 (29.3%) has family history of DM, 23 (21.7%) have history of GDM in previous pregnancy and 24(22.6%) have history of PCOD.

In our study, correlation of different HbA1c levels of first and second trimester & DIPSI positive cases were highly significant (P value 0.0000001 & P value 0.00000008). In our study correlation of different HbA1c levels of first trimester & OGTT positive case were highly significant (P value 0.000008). In our study cut off value for HbA1c is 5.5% in first trimester because at this cut off, we got the sensitivity of 90% without compromising specificity which is 80%. PPV of HbA1c is 94.7% and negative predictive value is 90.9% in diagnosis of GDM in first trimester by WHO-2013 OGTT criteria. Maximum number of OGTT positive patients has HbA1c levels between 5.4% to 6.1%. A lot of studies have been conducted to find a correlation between the two parameters.

**Table 4: Summary of studies regarding the ability of HbA1c to predict GDM**

| **STUDY** | **STUDY DESIGN** | **HbA1c** (%) | **SPECIFI-CITY** (%) | **SENSITI-VITY** (%) | **PPV** | **NPV** | **OGTT CRITERIA** |
|---|---|---|---|---|---|---|---|
| Present study | Prospective observational | 5.5 | 80 | 90.1 | 94.7 | 90.9 | WHO2013 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sujithra Det al(2018)[7] | Prospective | ≥5.7 | 93.2 | 70.4 | 79.2 | 89.54 | IADPSG/ WHO2013 |
| Shashikala et al(2020)[8] | Prospective observational | 5.55 | 83.6 | 55.7 | 41.5 | 83.7 | IADPSG |
| Poo ZX et al(2019)[9] | Pilot | 5.2 | 72 | 82 | 27 | 97 | |
| Arbib N et al(2019)[10] | Retrospective | 5.45 | 69 | 83.3 | 53 | 90.8 | |
| Jianbin Sun et al(2021)[11] | Prospective Cohort | >5.3 | 89.67 | 33.33 | | | IADPSG |
| Benaiges D et al(2017)[12] | Prospective observation | 5.6 | 89.3 | 32.9 | 31.6 | | |
| Renz PB et al(2015)[13] | Prospective observational | 5.5 | 82.9 | 50.6 | | | WHO 1999 OR ADA/ WHO 2013 |
| Khalafallah A et al(2016)[14] | Prospective Cohort | 5.4 | 95.4 | 26.5 | 41.9 | 91.2 | IADPSG |
| Wu K et al(2018)[15] | Cohort | 5.55 | 99.8 | 4.7 | 83.3 | 85 | IADPSG |
| Rajput R et al(2012)[16] | Prospective observational | ≥5.4 | 85.7 | 61.1 | | | ADA |
| Shrivastava N et al(2019)[17] | Cross sectional | 5.5 | 84.9 | 98.6 | | | ADIPS |
| Sevket O et al(2014)[18] | Prospective observational | ≥5.2 | 67.48 | 64.15 | | | IADPSG |

Sujithra D et al study (2018)[7] with HbA1c ≥5.7, sensitivity was 70.4%, specificity was 93.2%, PPV was 79.2%, NPV was 89.5% for first trimester before 12 weeks. This study concluded that women with higher HbA1c (≥5.7) were more likely to develop GDM than those women with lower HbA1c (≤5.7).This study stated that HbA1c can be used as early as 12 weeks for predictor of GDM.

Shashikala et al (2020)[8] study concluded that in early pregnancy HbA1c can be used as screening tool.HbA1c >5.5% warrants an early OGTT for diagnosis and treatment of GDM. HbA1c>5.15% with 80% sensitivity would call for vigilance and repeat OGTT at 24 weeks and 34 weeks. With>5.55% HbA1c, specificity was 83.6% and PPV was 41.5% and NPV of 83.7%. The mean HbA1c of GDM positive cases was 5.68 ± 0.69% while 5.25 ± 0.38% with p-value <0.001.

Poo ZX et al (2019)[9] pilot study demonstrated that a first trimester HbA1c of 5.2% (33 mmol/mol) had a sensitivity of 82.4% and a specificity of 71.6%, NPV of 96.9% and PPV of

27.2% for the prediction of GDM among Singaporean women. They concluded that if first trimester HbA1c is < 5.2%, then there is no need to do screening in second trimester in low-risk Singaporean women while those with HbA1c ≥ 5.2% would need a further confirmatory OGTT between 24 and 28 weeks of gestation.

Arbib N et al (2019)[10] retrospectively analyzed the first trimester HbA1c of 142 women who delivered in tertiary medical centre in Petach Tikva, Israel. They concluded that HbA1c ≥5.45% predicted gestational diabetes with 83.3% sensitivity, 69% specificity with PPV 53% and NPV 90.8%.

Jinabin Sun et al (2021)[11] study, HbA1c levels in the first trimester were significantly higher in the GDM group. The positive likelihood ratio was the highest at HbA1c 5.9% with sensitivity 2.78 % and specificity was 99.83%.The risk of GDM was significantly increased in pregnant women with first-trimester HbA1c levels >5.9% and lowest at <4.4% HbA1c.They advised lifestyle modifications as early as possible in women with HbA1c >5.9% in first trimester to decrease adverse pregnancy outcomes.

Renz PB et al (2015)[13], analyzed that the at the cut off value of HbA1c 5.8% the sensitivity and specificity of HbA1c as a predicting marker for GDM is 26.4% and 94.9% respectively. He concluded that different HbA1c cutoff points in combination with the screening test may be used as a diagnostic tool for GDM.

Khalafallah A et al (2016)[14] found that with the HbA1c cut off ≥5.4% in third trimester can be used as a predictor of GDM. At this cut off value of HbA1c the sensitivity and specificity were 27% and 95% respectively and NPV was 91%. They concluded that high NPV makes it a useful screening test and to reduce burden of testing.

Wu K et al (2018)[15], carried out a prospective study on 690 women. At HbA1c cut off ≥5.2% combined with haematocrit to diagnose GDM shows specificity of 96.6%, sensitivity of 13.3%, PPV of 50% and NPV of 81.6%. The area under the curve for GDM detection using HbA1c alone was 0.563 and increased to 0.640 after combining HbA1c and hematocrit. They concluded that hematocrit combined with HbA1c shows a significant positive correlation with HOMA-IR.

Rajput R et al study (2012)[16] showed that HbA1c of 5.45% had a higher sensitivity (85.7%) in detecting GDM but the specificity was low (61.1%). If HbA1c value of ≥5.95% is used to diagnose GDM then it increased specificity to 97.2% but sensitivity was lowered to 28.6%. They stated that HbA1c cannot replace OGTT for diagnosis of GDM but it can be used in combination with OGTT to obviate the need of OGTT in large number of pregnant women which is more cumbersome, time consuming and shows intra individual variation.

Shrivastava N et al study (2019)[17] showed that at 24-28 weeks a cut off value of HbA1c was 5.5%, the specificity was 84.9% and the sensitivity was 98.6% in predicting GDM. The range of HbA1c in DIPSI positive patients was 5.5% to 6%. This study concluded that HbA1c can be used as predictor for GDM, but further confirmation can be done by a study with large sample size. The cutoff value is similar to our study but this value is for second trimester in comparison to our study in which we have taken HbA1c cut off value for diagnosing GDM in first trimester.

Sevket O et al study(2014)[18], showed HbA1c ≥5.2% had sensitivity of 64.15% and specificity of 67.48% in diagnosing GDM, and a positive predictive value of 26.77%.They concluded that HbA1c is not suitable to use alone for the diagnosis of GDM.

## CONCLUSION

In this study at first trimester HbA1c value 5.5% shows specificity of 80% and sensitivity of 90% with negative predictive value of 90.9% and PPV value of 94.7% in diagnosis of GDM with WHO 2013 criteria. The sensitivity and PPV of HbA1c at 5.5% for GDM was high. On

the basis of above observation, our study supports that first trimester HbA1c can be employed as a predictive biomarker for GDM.
The risk of developing GDM was significantly increased in women with first trimester HbA1c >5.5% in our study. Pregnant women with normal DIPSI but HbA1c ≥5.5% would need OGTT in second trimester between 24-28 weeks to confirm GDM. Women with higher HbA1c can benefit from interventions like appropriate diet and lifestyle modification early in pregnancy. This helps in preventing long term sequelae of GDM and adverse pregnancy as well as perinatal outcomes.
Limitation of our study was that samples were selected from high-risk group for GDM which reduced the generalizability of the study. The cost factor is a significant hurdle in Indian settings as HbA1c is expensive than glucose-based tests. HbA1c alone cannot replace OGTT as confirmatory test to diagnose GDM due to low specificity.
A multicentric study involving stratified sampling can be recommended to determine a cut off value of HbA1c to exclude GDM.

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