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A prospective study on first trimester hba1c as predictor of gestational diabetes mellitus

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Abstract

Throughout pregnancy, maternal adaptations occur in multiple systems, including cardiovascular, respiratory, and metabolism. Aim of these maternal adaptations is to maintain a healthy balance between the mother and fetus while ensuring proper fetal development. In the context of glucose metabolism, these adaptations occur to ensure adequate shunting of glucose to promote fetal development while maintaining adequate maternal nutrition. After taking informed written consent, antenatal women attending Antenatal clinic of Department of Obstetrics and Gynaecology during 8-14 weeks of gestation, fulfilling the inclusion criteria, were enrolled as study subjects. A standard performa was given to all patients meeting the inclusion criteria. Performa included demographics, obstetric history, past history, family history, auxology, 1st trimester HbA1C values, 2nd trimester GTT results and USG, 3rd trimester GTT and USG results, baby details. HbA1c was done routinely with other 1st trimester routine investigations. An ROC curve was constructed for the study sample to estimate the cutoff of HbA1c to predict GDM, and from the ROC curve the optimum cut off for predicting GDM in this study population was obtained as 5.55% which has a sensitivity of 86%, specificity of 77%, PPV of 46.6% and NPV of 96%. The area under the ROC curve was found to be 0.85 which indicate HbA1c has good predictive value for GDM.

Keywords: First Trimester, HbA1c, Gestational Diabetes Mellitus

Introduction

The prevalence of GDM in a population reflects the prevalence of type-2 diabetes within that population. The global prevalence of GDM varies widely from 1 to 28% depending on population characteristics, screening methods, and diagnostic criteria. The International Diabetes Federation (IDF)-2015 report showed that about 16.2% of women had some form of hyperglycemia during pregnancy, of which GDM shares about 85.1% of the load. A review revealed the prevalence varies from 5.4% in Europe to 11.5% in Asia. Similarly, the IDF report indicated that there were regional differences in the magnitude of hyperglycemia during pregnancy, for instance, the South-East Asia region had higher (24.2%) as compared to 10.5% of the Africa Region ^[1, 2].

Throughout pregnancy, maternal adaptations occur in multiple systems, including cardiovascular, respiratory, and metabolism. Aim of these maternal adaptations is to maintain a healthy balance between the mother and fetus while ensuring proper fetal development. In the context of glucose metabolism, these adaptations occur to ensure adequate shunting of glucose to promote fetal development while maintaining adequate maternal nutrition. Initially during gestation, fasting blood glucose levels drop, in part, due to dilutional effects as maternal blood volume increases, remain constant in the second trimester, and further decrease during the third trimester. Increased glucose utilization by the fetal-placental unit throughout pregnancy, removing glucose from the maternal circulation, also contributes to the decline ^[3]. During this period of increased glucose utilization by the fetal-placental unit, maternal insulin sensitivity decreases. To compensate for these changes, both maternal hepatic gluconeogenesis and fatty acid levels increase ⁽¹⁾. While gravid fasting blood glucose levels remain lower than pregravid fasted levels, postprandial glucose levels are elevated relative to the pregravid state. This elevation is likely a result of impaired insulin action, leading to diminished postprandial glucose utilization by the mother. Other contributing factors may include altered pancreatic β -cell-mediated insulin secretion and hepatic gluconeogenesis ^[4].

HbA1c is the product of an irreversible non-enzymatic binding of glucose to plasma proteins, specifically hemoglobin (Hb).

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The mean plasma glucose over the erythrocyte life span is correlated with a degree of glycosylation. It is a single, non-fasting blood test and reflects glucose levels over the previous 4-8 weeks. As compared with glucose testing, it has been shown to have greater reliability with <6% inter-laboratory variation. Thus, HbA1c test has improved analytical stability with greater standardization between assays and less pre-analytical variation. Further comparisons with fasting blood glucose and 2 h postprandial glucose have shown HbA1c to have less intra individual variation as it does not appear to be affected by diurnal variation, meals, fasting, acute stress or by the large number of common drugs known to influence glucose metabolism [5, 6].

Methodology

Study Design: Prospective study

Study Setting: Study was conducted on patients attending Gynaecology OPD of SATH

Study Period: One year, after obtaining clearance from the Institute Research Committee and Institutional Human Ethics Committee

Study Subjects: Antenatal cases attending the antenatal clinic of SAT, Hospital

Inclusion criteria

- 8-14 weeks of gestation
- Singleton pregnancy

Exclusion criteria

- Known case of diabetes mellitus
- 1st trimester HbA1c >6.0
- Concurrent medical illnesses as hypertension, renal disease other diseases

Study Variables

- Demographic variables as age (years)
- BMI (kg/m²)
- Parity
- Obstetric history
- Family history of diabetes
- 1st trimester HbA1c
- 75 g OGTT
- Mode of delivery
- Gestational age at delivery
- Baby birth details: Birthweight (kg), APGAR
- Gestational diabetes

Sampling Technique

All consecutive antenatal women between gestational age 8-14 weeks attending the antenatal clinic of SATH

Data collection technique

After taking informed written consent, antenatal women attending Antenatal clinic of Department of Obstetrics and Gynaecology during 8-14 weeks of gestation, fulfilling the inclusion criteria, were enrolled as study subjects.

A standard performa was given to all patients meeting the inclusion criteria. Performa included demographics, obstetric history, past history, family history, auxology, 1st trimester HbA1c values, 2nd trimester GTT results and USG, 3rd

trimester GTT and USG results, baby details. HbA1c was done routinely with other 1st trimester routine investigations.

The study subjects were followed up till delivery. 75 g OGTT was performed at 24-28 weeks and if negative at 24-28 week, GTT was repeated between 32-36 weeks.

Based on IADPSG criteria they were grouped as Normal & GDM.

HbA1c was measured in 2ml of EDTA whole blood sample that was stored at <-70°C and thawed immediately before analysis.

HbA1c was measured using Bio-Rad D10/ HPLC method

The result were expressed in NGSP units.

75 g OGTT was done by the glucose oxidase method

Ethical considerations

- Written informed consent were obtained from the participants
- Confidentiality and privacy was maintained throughout the study
- No additional expenses were incurred for the patient as part of the study

Data analysis

Data were entered into Microsoft excel

Continuous variables were estimated using mean and standard deviation. Nominal data were expressed as frequency. Appropriate statistical tests like t test, chi square test, were done to know the correlation between the variables.

ROC curve was constructed to assess discriminative capacity of HbA1c for detection of GDM.

Sensitivity, Specificity, Predictive values were calculated.

Results

Figure 1: ROC curve of HbA1C to assess the optimum cut off value of HbA1c to classify GDM and Non GDM

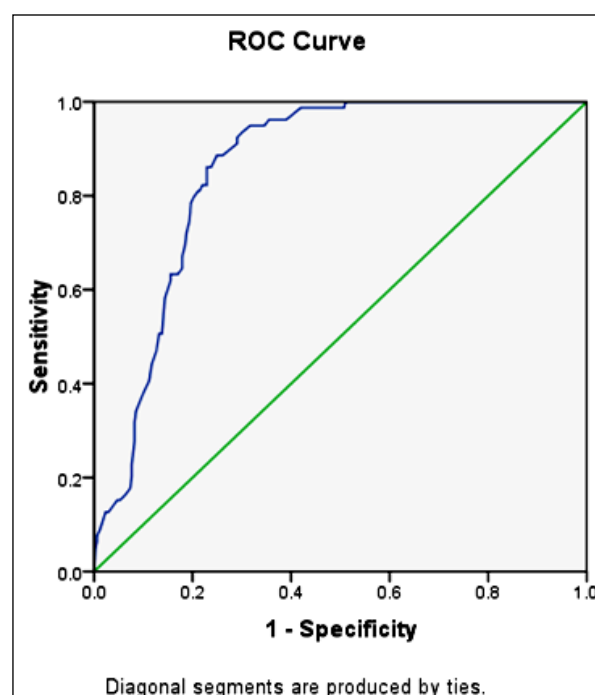


Table 1: The ROC curve characteristics

Area under the ROC curve (AUC)	
Area under the ROC curve (AUC)	0.856
Standard Error a	0.018
95% Confidence interval b	0.820 to 0.892

Table 2: ROC curve cut offs

Criterion	Sensitivity	Specificity	+LR	-LR	+PV	-PV
>5.54	86.08	76.25	3.62	0.18	45.6	95.9
>5.55	86.08	77.13	3.76	0.18	46.6	96.0
>5.57	82.28	77.13	3.60	0.23	45.5	94.9
>5.58	82.28	78.01	3.74	0.23	46.4	95.0
>5.59	81.01	78.59	3.78	0.24	46.7	94.7

An ROC curve was constructed for the study sample to estimate the cutoff of HbA1c to predict GDM, and from the ROC curve the optimum cut off for predicting GDM in this study population was obtained as 5.55% which has a sensitivity of 86%, specificity of 77%, PPV of 46.6% and NPV of 96%. The area

under the ROC curve was found to be 0.85 which indicate HbA1c has good predictive value for GDM. The subjects in the study sample was categorized into two groups; Group A: with HbA1c value $\geq 5.55\%$ and Group B: subjects with HbA1c value $< 5.55\%$.

Table 3: Association between Age and HbA1c

Independent variable		HbA1c		Total	χ^2	Odds ratio (95% CI)	p value
		≥ 5.55 (n=149)	< 5.55 (n=271)				
age	>25 years	81 (49.7%)	82 (50.3%)	163(100%)	23.52	2.74 (1.81 - 4.15)	<0.001
	≤ 25 years	68 (26.5%)	189 (73.5%)	257(100%)			
Total		149(100%)	271(100%)				

In the study population, among subjects with age >25 years 49.7% had HbA1c value $\geq 5.55\%$ and subjects with age ≤ 25 years who had HbA1c value $\geq 5.55\%$ were 26.5%. There was

statistically significant difference in both groups. With increasing age (>25 years) there is 3 times more chance of elevated HbA1c.

Table 4: Association between BMI and HbA1c

Independent variable		HbA1c		Total	χ^2	Odds ratio (95% CI)	p value
		≥ 5.55 (n=149)	< 5.55 (n=271)				
BMI	≥ 25	43 (62.3%)	26 (37.7%)	69(100%)	25.9	3.82 (2.23 - 6.54)	<0.001
	< 25	106 (30.2%)	245 (69.8%)	351(100%)			
Total		149(100%)	271(100%)				

Among subjects with BMI >25, 62.3% had HbA1c value $\geq 5.55\%$ where as in subjects with BMI < 25 , 30.2% had HbA1c $\geq 5.55\%$. There was statistically significant difference

between two groups. Women with BMI > 25 had 3 times more chance of elevated HbA1c.

Table 5: Association between Family h/o DM and HbA1c

Independent variable		HbA1c		total	χ^2	Odds ratio (95% CI)	p value
		≥ 5.55 (n=149)	< 5.55 (n=271)				
Family h/o DM	Yes	18 (64.3%)	10 (35.7%)	28(100%)	10.8	3.58 (1.61-7.98)	0.001
	No	131 (33.4%)	261 (66.6%)	392(100%)			
Total		149(100%)	271(100%)				

In subjects with family history of diabetes 64.3% had elevated HbA1c ($\geq 5.55\%$) whereas in subjects without family history of diabetes 33.4% had HbA1c $\geq 5.55\%$. The association was

statistically significant. Women with family history of diabetes have 3 times more chance of elevated HbA1c.

Table 6: Association between HbA1c values and GDM

HbA1c	GDM		χ^2	Relative Risk (95% CI)	p value
	Yes (n=79)	No (n=341)			
≥ 5.55	68 (45.6%)	81 (54.4%)	10.8	11.24 (6.14 - 20.58)	<0.001
< 5.55	11 (4.1%)	260 (95.9%)			

In the group with HbA1c $\geq 5.55\%$, 45.6% subjects were diagnosed with GDM and in the group with HbA1c $< 5.55\%$, only 4.1% was diagnosed with GDM. There is statistically significant

association between HbA1c and GDM. Subjects with HbA1c $\geq 5.55\%$ have 11 times more risk of developing GDM.

Table 7: Association between HbA1c values and Gestational age of diagnosis of GDM

HbA1c	Gestational age of diagnosis of GDM (weeks)		χ^2	p value
	24-28 (n=47)	32-36(n=32)		
≥ 5.55	42 (61.8%)	26 (38.2%)	1.045	0.243
< 5.55	5(45.5%)	6 (54.5%)		

In group with HbA1c $\geq$ 5.55%, 61.8% of the patients were diagnosed with GDM between 24-28 weeks compared to 45.5%

subjects with HbA1c<5.55%. There was no statistically significant difference between the two groups.

Table 8: Association between HbA1c values and Diabetic status

HbA1c	Diabetic status		χ^2	p value
	GDM on MNT (n=60)	GDM on INSULIN (n=19)		
$\geq$ 5.55	51 (75%)	17 (25%)	0.241	0.476
<5.55	9 (81.8%)	2 (18.2%)		

In the study population, 25% subjects in group with HbA1c $\geq$ 5.55% required insulin to control diabetes compared to 18.2%

subjects in group with HbA1c <5.55%. the difference was not statistically significant.

Table 9: Association between HbA1c values and Third trimester scan

HbA1c	Polyhydramnios in third trimester scan		χ^2	Relative Risk (95% CI)	p value
	Present present(n =14)	Absent (n=406)			
$\geq$ 5.55	12(8.1%)	137(91.9%)	15.96	10.9(2.47-48.11)	<0.001
<5.55	2(0.7%)	269 (99.3%)			

In the study population, in the group with HbA1c $\geq$ 5.55%, 8.1% subjects were detected to have polyhydramnios in third trimester scan compared to 0.7% subjects in the group with HbA1c

<5.55%. The difference between the two groups was statistically significant. Women with HbA1c $\geq$ 5.55% have 11 times more risk for developing polyhydramnios

Table 10: Association between HbA1c values and Mode of delivery

HbA1c	Mode of delivery		χ^2	Relative Risk(95% CI)	p value
	Caesarean (n=131)	Vaginal (n=289)			
$\geq$ 5.55	71 (47.7%)	78(52.3%)	29.1	2.15(1.62-2.84)	< 0.001
<5.55	60 (22.1%)	211 (77.9%)			

In group with HbA1c $\geq$ 5.55%, 47.7% had caesarean section where as in the group with HbA1c<5.55%, 22.1% had caesarean section. There is statistically significant association between

HbA1c values and Mode of delivery. Subjects with HbA1c $\geq$ 5.55% have 2 times more risk of need for caesarean section.

Table 11: Association between HbA1c values and Birth weight

HbA1c	Birth weight		χ^2	p value
	>4 kg (n=3)	<4 kg (n=417)		
$\geq$ 5.55	2 (1.3%)	147 (98.7%)	1.28	0.288
<5.55	1(0.4%)	270(99.6%)		

In the group with HbA1c $\geq$ 5.55%, 1.3% of the babies born, had birth weight more than 4kg and in the group with HbA1c<5.55%, 0.4% of the babies born had birth weight more

than 4 kg. There was no statistically significant difference between the two groups.

Table 12: Association between HbA1c values and Preterm birth

HbA1c	Term /preterm birth		χ^2	p value
	Preterm (n=32)	Term (n=388)		
$\geq$ 5.55	8 (5.4%)	141 (94.6%)	1.66	0.136
<5.55	24 (8.9%)	247 (91.1%)		

In the group with HbA1c $\geq$ 5.55%, 5.4% of babies born were preterm whereas in the group with HbA1c<5.55%, 8.9% babies were born preterm. There was no statistically significantly

difference between the two groups regarding incidence of preterm births.

Table 13: Association between HbA1c values and IBN admission

HbA1c	IBN admission		χ^2	Relative risk (95% CI)	p value
	Yes (n=30)	No (n=390)			
$\geq$ 5.55	17 (11.4%)	132 (88.6%)	6.33	2.37 (1.18 -4.76)	0.011
<5.55	13 (4.8%)	258 (95.2%)			

In the group with HbA1c $\geq$ 5.55%, 11.4% of the babies born required IBN admission whereas in the group with HbA1c <5.55% only 4.8% babies required IBN admission for various

reasons. There was statistically significant difference in two groups. Babies born to subjects with HbA1c $\geq$ 5.55% had 2 times more risk of IBN admission.

Table 14: Association between HbA1c values and Birth Asphyxia

HbA1c	Birth Asphyxia		χ^2	p value
	Yes (n=9)	No (n=411)		
≥5.55	4 (2.7%)	145 (97.3%)	0.323	0.403
<5.55	5 (1.8%)	266 (98.2%)		

In the group with HbA1c ≥5.55%, 2.7% babies born had birth asphyxia (APGAR <7 at 5 minutes) and in the group with HbA1c <5.55%, 1.8% babies born had birth asphyxia. However the difference between the groups was not statistically significant.

Discussion

In the study 3.3% women had evidence of polyhydramnios in third trimester scan. 8.1% women with HbA1c >5.55% had polyhydramnios in third trimester scan compared to 0.7% women with HbA1c values <5.55%. Difference between the two groups was statistically significant with p value <0.001. Women with elevated HbA1c value has 10 times more risk of polyhydramnios (RR 10.9 95%CI 2.47-48.11; p=<0.001)

In a study by Kaur N *et al.* showed that there was statistically significant increased incidence of polyhydramnios with HbA1c ≥5.8% (p=0.015). The cutoff of HbA1c in the study was however slightly higher than my study [7].

In another study by Sen Gupta *et al.*; there was significant increase in incidence of polyhydramnios when HbA1c level is >6% in 2nd and 3rd trimester, in patients with GDM.

In the study population, 68.8% women delivered vaginally and 31.2% subjects underwent caesarean section. 47.7% of women with elevated HbA1c had to undergo caesarean section compared to 22.1% women with HbA1c <5.55%. The difference was statistically significant indicating women with HbA1c ≥5.55% has 2 times more risk of need for caesarean section (RR 2.15 95%CI 1.62-2.84; p=<0.001).

In a study by Wendland *et al.* described risks of GDM according to the WHO criteria from 1999 and the International Association of Diabetes in Pregnancy Study Groups (IADPSG) criteria. Significant risk ratios for caesarean delivery using the respective criteria were 1.4 and 1.2 [8].

In the study population, 60.5% subjects delivered between 37-38 weeks, 31.9% subjects delivered between 38-40 weeks, 7.6% delivered at less than 37 weeks. Average gestational age of delivery in the study sample was 38 ± 1.19 weeks. In the group with HbA1c ≥5.55%, 5.4% were preterm deliveries compared to 8.9% in the group HbA1c <5.55%. The difference was not statistically significant.

In my study, in the group with HbA1c ≥5.55%, 5.4% of babies born to the were preterm and in the group with HbA1c <5.55%, 8.9% babies born were preterm. There was no statistical significant difference between the groups. This was in accordance with the study by Kaur N *et al.* which showed that there was no statistical significant difference in the incidence of preterm labor in group with elevated HbA1c >5.8% compared to those with HbA1c <5.8% [8].

In the study population majority of the babies born i.e 73.3% had birth weight between 2.5-2.99 kg. The mean birth weight in the study population was 2.80 ± 0.30 kg. In women with HbA1c ≥5.55%, 1.3% babies born were macrosomic compared to 0.4% babies in the group with HbA1c <5.55%. The study did not show any statistical significant association between HbA1c and birth weight. In contrary, a study by Mane.L *et al.* found that an HbA1c ≥5.7% was associated with increased risk of macrosomia [9].

Out of the total babies born, 7.2% babies needed IBN admission

for various reasons as low birth weight, birth asphyxia, respiratory distress, preterm etc. In the group with HbA1c ≥5.55%, 11.4% babies required IBN admission compared to 4.8% in the group with HbA1c <5.55%. There was statistically significant association of HbA1c with IBN admission indicating that babies born to subjects with elevated HbA1c values have 2 times more risk of IBN admission (RR 2.32 95%CI 1.29-4.16; p=0.001) In a study by Yi-Ran Ho *et al.* higher HbA1c levels (5.0-5.4, 5.5- 5.9, 6.0-6.4, 6.5-6.9, and >7.0%) were significantly associated with increased risks of admission to the neonatal intensive care unit (the odds ratio [OR] ranges were 0.88-3.15) [10].

Out of the 420 babies born, 2.1% babies had birth asphyxia (APGAR <7 at 5 minute). In women with HbA1c >5.55%, 2.7% babies had birth asphyxia and in the group with HbA1c <5.55%, 1.8% babies had birth asphyxia. There was no statistically significant difference in the incidence of birth asphyxia between both groups.

Conclusion

First trimester HbA1c ≥5.55% has a sensitivity of 86%, specificity 77%, PPV of 46.6% and NPV of 94% and is useful in predicting pregnant women who develops GDM, so the women can be given appropriate advice of diet and lifestyle modification early in pregnancy.

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