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Original Research Article

Glycated haemoglobin versus oral glucose tolerance test in screening for gestational diabetes mellitus

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ABSTRACT

Background: Glycated haemoglobin (HbA1c) has been documented as an easier, useful tool in diagnosis of diabetes and can be considered as a screening tool in GDM as compared to oral glucose tolerance test (OGTT) which has practical constraints like long waiting period in fasting, too many pricks and non-compliance to glucose load solution. The objective of the study was to find out the utility of HbA1c as a diagnostic tool when compared with OGTT in screening of GDM.

Methods: A retrospective study was conducted at Sri Venkateswara Medical College, Hospital and Research Center, Puducherry including 500 antenatal women attending to the Department of Obstetrics and Gynaecology for their antenatal checkup during the period from August 2016 to April 2018. HbA1c levels were estimated and ROC curve analysis was done to estimate sensitivity and specificity against gold standard OGTT.

Results: The HbA1c levels among the study subjects varied from 4.3% to 8.2%. The mean HbA1c levels among those diagnosed as GDM by gold standard OGTT was $5.82 \pm 1.1\%$ and among those without GDM was $5.13 \pm 0.7\%$. The area under the ROC curve was 0.773 (95% CI 0.732–0.814). An HbA1c cut-off value of $\geq 5.91\%$ had sensitivity of 34.6% and Specificity of 98.2% in diagnosing GDM. An HbA1c cut-off value of $\geq 5.32\%$ had sensitivity of 84.8% and specificity of 60.1% in diagnosing GDM.

Conclusions: HbA1c levels cannot substitute OGTT in diagnosis of GDM. A higher specific cut-off HbA1c value of $\geq 5.95\%$ is diagnostic of GDM.

Keywords: HbA1c, OGTT, Gestational diabetes mellitus, Sensitivity and specificity

INTRODUCTION

Gestational diabetes mellitus (GDM), defined as hyperglycaemia first evident during pregnancy, is a potential risk factor affecting both maternal and fetal outcomes of pregnancy.¹ The mothers with GDM are at risk of developing many serious obstetric complications such as increased need for Caesarean sections, growth abnormalities in the fetus like macrosomia, labour difficulties like shoulder dystocia, birth injury, and prematurity in addition to risk of long-term implications

in maternal and child well-being.² The gold standard test recommended for diagnosis of GDM is oral glucose tolerance test (OGTT). But it has some practical difficulties to the pregnant women like staying in fasting state overnight, two or three pricks at short intervals, 2-3 hours of waiting period during sample collection and sometimes nauseating sensation on drinking the glucose load solution. This obviates the need for a universally accepted, easily available, simpler diagnostic method for the diagnosis of GDM. American Diabetes Association (ADA) and World Health Organization (WHO) have

published the reliability of Glycated Haemoglobin (HbA1C) estimation in the diagnosis of Diabetes.^{3,4} Various studies around the globe have inconsistently documented the usefulness of HbA1c as a screening tool for GDM in pregnancy.⁵⁻⁸ This study aims at evaluating the efficacy of HbA1C in diagnosing GDM when compared with the gold standard OGTT.

METHODS

This retrospective study included 500 antenatal women attending to the Department of Obstetrics and Gynaecology, Sri Venkateswara Medical College, Hospital and Research Center, Puducherry for their antenatal checkup during the period from August 2016 to April 2018. The sample size calculated was based on a prevalence of 16.5% as estimated by a previous Indian study, a relative precision of 20% and an alpha of error 5%.¹⁰ The women included in the study were in their 24-28th of gestational age when they were called for blood glucose estimation after informing them about the study and consent obtained.

Women with known history of diabetes mellitus, pancreatic disorders, anaemia, chronic kidney diseases, hemoglobinopathies and other severe illness were excluded from the study.

The women were instructed to come for blood sample collection with minimum 8 hours (but not exceeding 14 hours) of overnight fasting. Venous blood samples were collected at fasting in EDTA tube for estimation of HbA1c and fasting blood sugar. HbA1c was estimated based on latex agglutination inhibition assay. A loading dose of 75gm of oral glucose solution was given following which blood sugar estimation was done at 1 hour and 2 hours post ingestion.

Statistical analysis

Data entry and analysis was done using SPSS Version 20.0. Student t-test was used to estimate differences between mean HbA1c levels. ROC curve was drawn to estimate sensitivity and specificity at different cut-off values of HbA1c. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 500 women were included in the study and majority (n=314, 62.8%) of them were in 21-25 years age group. The baseline characteristics of the study participants are shown in Table 1.

The HbA1c levels among the study subjects varied from 4.3% to 8.2%. The mean HbA1c levels among those diagnosed as GDM by gold standard OGTT was $5.82 \pm 1.1\%$ and among those without GDM was $5.13 \pm 0.7\%$. There is a significant difference of HbA1c values among those with and without GDM ($p < 0.001$).

According to the recently proposed International association of diabetes and pregnancy study group (IADPSG) criteria, the 145 (29%) of the study participants were classified as GDM.⁹

Table 1: Baseline characteristics of the study population (n=500).

Participant characteristics	Frequency	Percentage
Age (years)		
16-20	90	18
21-25	314	62.8
26-30	88	17.6
>30	8	1.6
Body mass index (Kg/m²)		
<18.5	195	39
18.6-23	255	51
>23	50	10
Parity		
0	206	41.2
1	198	39.6
2	75	15
≥3	21	4.2

ROC curve was used to depict the sensitivity and specificity of HbA1c in diagnosing GDM as defined by IADPSG criteria (Figure 1). The area under the curve was 0.773 (95% CI 0.732–0.814) designating HbA1c as a fairly good diagnostic test comparable to OGTT.

It was observed that an HbA1c cut-off value of $\geq 5.91\%$ had sensitivity of 34.6% and Specificity of 98.2% in diagnosing GDM. An HbA1c cut-off value of $\geq 5.32\%$ had sensitivity of 84.8% and specificity of 60.1% in diagnosing GDM. The former can be used as a diagnostic cut-off value whereas the latter can be used as a screening cut-off value to be confirmed by OGTT.

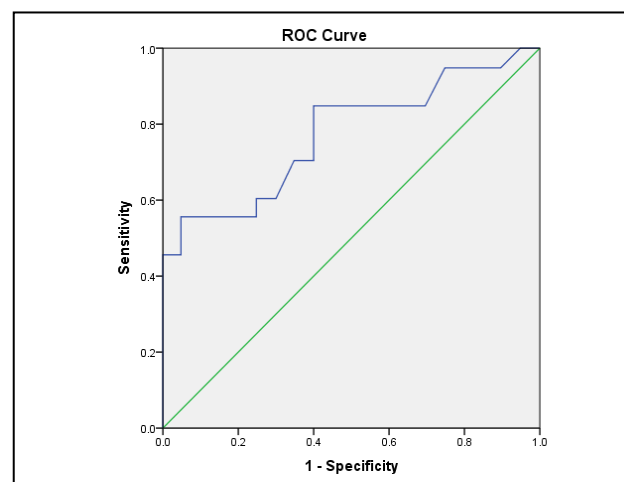


Figure 1: ROC curve showing the sensitivity and specificity of HbA1c in detecting GDM using ADA criteria.

DISCUSSION

An HbA1c level represents the summation of glucose variability in the past 3 months and is a reliable determinant of diabetes compared to the one day blood sugar status determined by fasting/post-prandial glucose estimation or OGTT as clarified by the American Diabetes Association.⁴ But in GDM, OGTT has remained the most reliable test. HbA1c levels have been different in those with and without GDM viz: $5.36 \pm 0.36\%$ among those with normal glucose tolerance and $5.96 \pm 0.63\%$ in those with GDM in the study done by Balaji et al.¹¹ In our study we found similar results showing a significant difference ($p < 0.001$) of HbA1c values among those with GDM ($5.82 \pm 1.1\%$) and those with normal glucose tolerance ($5.13 \pm 0.7\%$). While measuring fasting blood sugar, the intra-individual coefficient of variation was found to be 6.4–11.4% and was still higher for measurement of 2-hours postprandial blood glucose ranging from 14.3 to 16.7%.¹² On the other hand, measurement of HbA1c has lower intra-individual coefficient of variation of 4.2% over the short term in persons with diabetes and 1.9% over the long term in persons without diabetes.¹² The present study documented an HbA1c cut-off value of $\geq 5.91\%$ had sensitivity of 34.6% and Specificity of 98.2% in diagnosing GDM. When the HbA1c cut-off value was lowered to $\geq 5.32\%$ the sensitivity was 84.8% and specificity was 60.1%. A similar study done by Rajput et al.¹² documented that an HbA1c cut-off value of $\geq 5.95\%$ had sensitivity of 28.6% and specificity of 97.2% in diagnosing GDM while an HbA1c cut-off value of $\geq 5.45\%$ had sensitivity of 85.7% and specificity of 61.1% in diagnosing GDM.¹³ Considering that a diagnostic test for GDM should have a greater specificity so that branding pregnancy related physiological hemodynamic and glycemic variabilities as GDM is prevented, a cut-off value of $\geq 5.95\%$ which has 97.2% specificity can be taken as GDM. A cut-off value of less than 5.45% can be taken as normal and any HbA1c value between 5.45 and 5.95 should be recommended to undergo an OGTT test for confirmation.

CONCLUSION

HbA1c levels cannot substitute OGTT in diagnosis of GDM. But to make the process of diagnosis less cumbersome and simpler a high specific cut-off HbA1c value of $\geq 5.95\%$ can be taken as GDM. A larger cohort study following-up HbA1c variability throughout pregnancy and comparing those values between GDM and normal pregnancy will fetch better information on usage of HbA1c as a diagnostic test in preference to OGTT in routine obstetric practice.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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