

Evaluation of HbA1c as a Diagnostic Tool for GDM

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Abstract

Gestation Diabetes mellitus is a condition which leads to unfavorable maternal as well as fetal outcomes. Although the traditional method of screening GDM in pregnant women by OGTT has been widely used and accepted for decades, but there is always a need for better and more easier test for diagnosis of GDM. In our systematic review we have critically appraised few published studies for the demonstration of HbA1c as a diagnostic tool for GDM. It is understood from all these studies HbA1c evaluation have various advantages over the traditional OGTT because of the high reproducibility and improved instrumentation and standardization of HbA1c assay, less biological variability and it is not affected by short term lifestyle changes. It can be used as a primary screening test for all the pregnant women as does not require extensive patient preparation and less time consuming. But once the HbA1c value falls above the reference range it is mandatory to perform a confirmatory test for the diagnosis of GDM. In near future HbA1c can be used as a marker for diagnosis.

Keywords: GDM; HbA1c.

Introduction

Gestation Diabetes mellitus is a condition which leads to unfavorable maternal as well as fetal outcomes.¹ Although the traditional method of screening GDM in pregnant women by OGTT has been widely used and accepted for decades, it is a cumbersome procedure for both patients as

well as the testing facility staff which puts all the pregnant women under the stress of long duration and inconvenience. Hence there is always a need for better and easier test for diagnosis of GDM.

Pregnancy being called a diabetogenic state is associated with increased risk of complications during antenatal period, during delivery and after delivery. Many studies have shown that the chances or risks of these unfavorable outcomes may be seen in healthy pregnant women in whom the glucose levels are within the normal range.²⁻⁷ There are no constant and proper standards that are universally accepted for the diagnosis of GDM.⁸ Hence there is a constant need for a simpler, easier and patient friendly test to detect or screen such complicated and one of the most frequent diseases of pregnancy, GDM.

The aim of the study is to systematically review available data focusing on the effectiveness of HbA1c as a diagnostic test for GDM.

Materials and Methods

We undertook this systematic critical appraisal of all the published studies on demonstrating the effectiveness of the test HbA1c in pregnant women in the diagnosis of GDM. Maximum number of articles was taken from Google scholar and PubMed. The keywords used for the search were "HbA1c" and "gestational diabetes"

A study conducted by Renzet al⁹ on 262 pregnant women who are in their third trimester to study for the effectiveness of HbA1c test a procedure for diagnosis of GDM. The results of their study were found to be as follows:

Table 1: Specificity and sensitivity measures of HbA1c with different cut-offs according to study by Renzet al⁹.

HbA1c cutoff	Specificity	Sensitivity
≥48 mmol/mol (6.5%)	100%	7%
≥40 mmol/mol (5.8%)	94.9%	26.4%
≥31 mmol/mol (5.0%)	32.6%	89.7%

In their study they concluded that with the cutoff point of 5.8%, HbA1c test alone can detect almost one third i.e. 38% of patients with GDM.

Min Ye et al¹⁰ conducted a retrospective study in 1959 pregnant women among whom 413 patients were having GDM. Their findings were given in the following tabular column.

Table 2: Specificity and sensitivity measures of HbA1c with different cut-offs according to study by Min Ye et al¹⁰.

HbA1c cutoff	Specificity	Sensitivity
<4.8%	85%	31.8%
>5.5%	14.8%	95.7%

They found that around 34.7% of women benefited with HbA1c as the screening test, instead of OGTT, in diagnosing GDM.

Mukesh M. Agarwal et al¹¹ did a study in 442 pregnant women who were evaluated for HbA1c. They have taken two threshold values for accommodating the patients in the GDM range who were later on confirmed by 75 gram OGTT. In their study group they found that 84 (19%) women had GDM and the remaining 358 (81%) were healthy pregnant women. When HbA1c cutoff was taken as <5.5% the sensitivity was 82.1% with 15 out of 90 women below threshold showing false-negative and when the cutoff was taken as >7.5% the specificity was found to be 95.8% with 15 out of 21 women above the threshold showing false-positive. They concluded that HbA1c alone can be used in 25.1% of women in whom the need for OGTT can be eliminated.

Patcharaporn Siricharoenchai et al¹² conducted a prospective observational study on 114 Thai pregnant women who are in the gestational age of more than or equal to 24 weeks and who had impaired 3-hour 100 gram oral glucose tolerance test (OGTT) to evaluate the sensitivity and specificity of HbA1c as a diagnostic test for GDM. Among the study subjects 35 women were diagnosed with GDM using National Diabetes Data Group for a 3-hour 100 gram OGTT when HbA1c cut off was

taken as ≥5.8%, the sensitivity was 17.1% but the specificity was 100% (Positive predictive value, negative predictive value and accuracy were 100%, 73.2% and 74.6% respectively). In this study they found that OGTT cannot be replaced by HbA1c for diagnosis of GDM. However the high specificity value shows that HbA1c evaluation can be used to reduce the unnecessary confirmation tests (100 gram OGTT) that the number of patients should undergo.

Alhossain Khalafallah et al¹³ conducted a prospective study by including 480 pregnant women with gestational age between 24 and 28 weeks to compare HbA1c levels and OGTT values in them for the diagnosis of GDM. They have found that 57(11.9%) women were diagnosed with GDM according to OGTT criteria. In this study they have studied the association of GDM with HbA1c taking different cut-off values and the results were as follows:

Table 3: Specificity and sensitivity measures of HbA1c with different cut-offs according to study by Alhossain Khalafallah et al¹³.

HbA1c cut-off values	Sensitivity	Specificity	Negative predictive value
≥ 5.1%	61%	68%	93%
≥ 5.4%	27%	95%	91%

By this they have concluded that OGTT can be given to pregnant women with an HbA1c value of ≥ 5.4%.

Srmshtty Sowmya et al¹⁴ conducted a prospective observational study to determine the role of HbA1c as a screening and diagnostic tool for GDM on 500 antenatal women with gestational age between 24 and 28 weeks. Among these study subjects GDM was diagnosed in 45(9%) women. They found that for the diagnosis of GDM when the cut-off was taken as 5.3%, the specificity was 51.6% but the sensitivity was 95.6%. So they concluded that about half of the pregnant women would have eliminated OGTT and the remaining 50% of the pregnant women in whom the HbA1c was abnormal require an OGTT for confirmation. Hence they have concluded that though OGTT cannot be replaced by HbA1c, evaluation of HbA1c can be used in about 50% of women as a screening test with a cut-off of 5.3% who need not undergo the burdensome OGTT.

Conclusion

While there are some minimum drawbacks in HbA1c estimation for the evaluation and diagnosis of GDM, its measurement has gained importance

and standard over the past few years. With the establishment of international targets and guidelines for its estimation it has now become one of the reliable tests in the diagnosis and monitoring GDM. Although it cannot replace OGTT in diagnosing GDM, because of the extreme convenience it offers to perform as well as to interpret the results, it can be used as a primary screening tool for GDM. The patients who fall below the cut-off value can be eliminated for OGTT and only those who are above this critical value need to undergo the confirmation test (OGTT). Thus it reduces the number of patients in whom OGTT need to be performed which significantly reduces the time factor, workload over the staff personnel, resources and mainly the burden on patients like overnight fasting and longer testing duration. In our review we conclude that more studies with larger study population and taking all the confounding factors into consideration should be undertaken to make HbA1c assessment more widespread.

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