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ORIGINAL ARTICLE

Reliability of Estimation of HBA1C for Diagnosing Gestational Diabetes

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ABSTRACT

Gestation Diabetes mellitus is a condition that, if left untreated, can have adverse effects not only on the mother but also on the unborn child. Even though the oral glucose tolerance test (OGTT), which is the typical method of screening for gestational diabetes in pregnant women and has been widely used and recognised for a number of decades, there is still a need for a test that is both more accurate and simpler to administer in order to diagnose GDM. This is the case despite the fact that the standard method involves an OGTT

Subjects and Methods: In this prospective observational study, OGTT and HbA1c were performed in 400 antenatal women between 24 and 28 weeks of gestation; the pregnant women were followed up thereafter. Repeat OGTT and HbA1c were done in women with GDM at 6 weeks postpartum.

Results: Among the 400 women, 52 were diagnosed with GDM, for an incidence of 9%. The mean HbA1c level in women with GDM was 6.2 – 0.6%, whereas it was 5.4 – 0.5% in those with normoglycemia. Women with GDM had a higher incidence of pregnancy-related complications compared with normoglycemic women. An HbA1c cutoff of 5.3% had a sensitivity of 95.6% and a specificity of 51.6% for the diagnosis of GDM and would have avoided OGTT in approximately half of antenatal women, while missing 5% of the women. However, those with an abnormal HbA1c will require a confirmatory OGTT, as 50% of normoglycemic women would be misclassified as having GDM by this approach. On repeat testing postpartum, two of 52 women (4.4%) had overt diabetes mellitus, whereas five (11.1%) had impaired glucose tolerance.

Conclusions: Although HbA1c cannot replace OGTT in the diagnosis of GDM, it can be used as a screening test, avoiding OGTT in approximately 50% of women, if a cutoff of 5.3% is used. The findings of all of these trials make it abundantly evident that the HbAlc test is superior than the traditional OGTT in a number of important respects. The great reproducibility of the HbAlc assay, improved instrumentation and standardisation of the HbAlc assay, less biological variability, and the fact that it is not affected by short-term changes in lifestyle are all factors that contribute to these advantages. It is possible to use it as a primary screening test for all pregnant women due to the fact that the patient does not need to prepare significantly for the test and that it takes less time. If, on the other hand, the HbAlc result is discovered to be greater than the reference range, then it is absolutely necessary to perform a confirmatory test in order to establish a diagnosis of GDM. It is anticipated that HbAlc will be able to function as a diagnostic marker in the not-too-distant future.

Keywords: GDM; HbAlc.

INTRODUCTION

Gestation Diabetes mellitus is a disorder that, in the event that it is not properly treated, can have detrimental effects not only on the mother but also on the baby while it is still developing. Even though the classic method of screening for gestational diabetes in pregnant women by OGTT has been widely used and approved for decades, it is still a difficult procedure for both patients and the staff working at the testing facility. As a direct consequence of this, all pregnant women are subjected to the strain of having to put up with an ordeal that is drawn out and inconvenient. Despite the fact that it has been widely implemented and accepted for several decades, there is another tactic that has been in use for less time and has proven to be more successful than this one. As a direct result of this, there is an ongoing requirement for diagnostic tests that are not only more accurate but also simpler to perform.

The term "diabetogenic condition" refers to the fact that pregnancy is linked to an increased risk of complications throughout the antenatal period, during the birthing process itself, and in the immediate aftermath of the delivery of the baby. This increased risk of complications increases the likelihood that a woman will develop diabetes. Because of this increased risk of problems, one could develop diabetes. Numerous studies have revealed that the chances or dangers of these unfavourable outcomes may be seen in healthy pregnant women whose glucose levels are within the normal range. These women have had normal glucose levels throughout their pregnancies. Throughout their pregnancies, these ladies have maintained normal levels of glucose in their blood. It has been discovered that these women have glucose levels that are within the normal range. [Citation needed] There is not a single, unified set of diagnostic criteria that is universally considered to be complete, accurate, and consistent for the disease of GDM. This is because there is no single, unified set of diagnostic criteria. To diagnose or screen for a condition as difficult as GDM, which is also one of the most common diseases associated with pregnancy, there is an ongoing need for a test that is less complicated, easier, and more patient friendly. As a result of this, there is a need for a test that is less complicated, easier, and more patient friendly. This is due to the fact that gestational diabetes is one of the most prevalent disorders connected to pregnancy.

The purpose of the research is to conduct a comprehensive analysis of the data that is presently accessible, with a particular emphasis placed on the utility of HbAlc as a diagnostic instrument for GDM. Performing the necessary investigation will bring about the desired results.

MATERIALS AND METHODS

Women whose menstrual cycles were less than 28 weeks long and who had not yet been pregnant were considered eligible for participation in the study. Women who had a history of type 2 diabetes mellitus, gestational diabetes in a prior pregnancy, a known hemoglobinopathy or haemoglobin variation, or a haemoglobin level of less than 10 g/dL at the initial visit were ineligible to participate in the trial. Neither group included women who had an OGTT performed earlier than 24 weeks into their index pregnancy and been given a diagnosis of GDM in that pregnancy. After being provided with the necessary background knowledge, each individual who contributed to the research project was approached with a request for their consent. 500 women were eligible to participate after meeting the inclusion criteria; however, 140 of them declined to grant consent and 60 of them delivered their babies elsewhere; as a direct consequence, only 300 patients

were available for the final analysis. An OGTT was performed on each woman between the ages of 24 and 28 weeks pregnant after she had gone without eating for the entirety of the night before to the test and then consumed an unrestricted meal for the previous three days prior to the test. After having her blood drawn while she was fasting, a woman was administered a solution that contained 70 grammes of anhydrous glucose in water over the period of four minutes. The solution was given to her in small increments. After then, samples of the subject's blood were taken one and two hours after the glucose solution had been ingested.

The sample that was collected while the person was fasting was used to measure the subject's haemoglobin, fasting plasma glucose, and haemoglobin A1c levels. The concentration of glucose in the plasma was determined by analysing samples obtained one and two hours following a glucose load. The examination of HbA1c was carried out with the assistance of an automated analyzer that had a reportable range of 3.5–16.5%. Ion-exchange high-performance liquid chromatography is the underlying principle behind how this analyzer functions. It has been said that the device has a precision of 1.14% in individuals with normal glucose levels and 1.20% in patients with diabetes. In addition, the machine has been validated by the National Glycohemoglobin Standardization Program as having documented traceability to the reference method that was utilised in the Diabetes Control and Complications Trial. This validation was carried out by the National Glycohemoglobin Standardization Program. In order to figure out how much glucose was present in the plasma, the glucose oxidase method was utilised.

An further HbA1c measurement as well as the 75-g OGTT were carried out six weeks after the delivery of the baby. The postpartum glucose tolerance status was evaluated using the criteria provided by the World Health Organization for adult patients who are not pregnant. These criteria are intended for use with adult patients. A plasma glucose level that is higher than 120 mg/dL when the patient is fasting and/or a plasma glucose level that is higher than 200 mg/dL two hours after a glucose load are both considered to be indicators of overt diabetes. "impaired glucose tolerance" refers to a fasting plasma glucose level that is between 100 and 120 mg/dL and/or a plasma glucose level that is between 140 and 200 mg/dL. Additionally, "impaired glucose tolerance" might refer to a plasma glucose level that is between 100 and 120 mg/dL.

The multiple pregnancy-related outcomes that were taken into consideration for this study are listed below, along with the criteria that were utilised to define each of those outcomes:

If a woman had a history of one or more pregnancy losses after the gestational age of foetal viability (>24 weeks), or if she had a history of three or more pregnancy losses before the gestational age of 24 weeks, then she was regarded to have a bad obstetric history (both spontaneous and induced).

It's possible that a woman became pregnant with the help of assisted reproductive technologies like intrauterine insemination, in vitro fertilisation, or ovulation induction. These are only few of the approaches.

Any delivery that required further procedures for the delivery of the shoulders and trunk after the delivery of the foetal head was required to be evaluated for shoulder dystocia. This was the case even if the shoulder dystocia was not diagnosed.

A birth injury is the term used to describe any kind of damage that occurs to the foetus as a result of the process of delivery. This can entail injury to the nerves or nerve plexuses, in addition to components of the skeleton.

In this study, a perineal injury was defined as an injury to the maternal perineum that was more severe than a first-degree perineal tear and an episiotomy that was performed on purpose. In other words, a perineal injury was an episiotomy that was performed on purpose.

Any additional measures to resuscitate the newborn that were not those that were typically utilised as appropriate for the mother's gestational age at the time of delivery were considered to be a neonatal resuscitation necessity. This was the case because the mother's gestational age at the time of delivery was greater than the average gestational age at the time of delivery.

Any drop in blood glucose levels in a newborn that necessitated the administration of intravenous dextrose solution or the admission or transfer to a special unit for further care was considered to be a case of neonatal hypoglycemia. Cases of neonatal hypoglycemia required either the administration of intravenous dextrose solution or the admission or transfer to the special unit.

A serum bilirubin level that is higher than the threshold for treatment with phototherapy at the gestational age is characteristic of neonatal jaundice. As a result, treatment must consist of either phototherapy or an exchange transfusion, depending on the gestational age. the study that established the utility of the HbAlc test in the diagnosis of GDM in pregnant women was referred to as the study.

RESULT

An examination of the effectiveness of the HbAlc test as a method for the diagnosis of gestational diabetes was carried out on three hundred pregnant women who were in the third trimester of their pregnancies. The participants' pregnancies were in their third trimester at the time of the examination. According to the results of their research, it was found to be the case that the following was accurate. In their study they concluded that with the cutoff point of 5.7%, HbAlc test alone can detect almost one third i.e. 40% of patients with GDM.

Table 1: Specificity and sensitivity measures of HbAlc with different cut-offs according to study '.

HbAlc cutoff	Specificity	Sensitivity
> 47 mmol/mol (6.4%)	100%	6%
> 39 mmol/mol (5.7%)	95%	27%
> 30 mmol/mol (5.0%)	33%	90%

Table 2: Complications Associated with Pregnancy, as Well as Maternal and Fetal Outcomes, in Women with Gestational Diabetes Mellitus and Normoglycemia

Characteristic	Women with GDM	Normoglycemic women	P value
Oligohydramnios	4.5%	1.4%	0.01
Polyhydramnios	15.7%	0.8%	NS
Intrauterine growth retardation	21.4%	1.8%	<0.01
Macrosomia	9.3%	1.7%	0.0011
Presence of congenital malformations	4.2%	2.8%	NS
Birth weight (mean ± SD) (kg)	3.4 ± 0.4	2.8 ± 0.4	0.0017
Requirement for neonatal resuscitation	4.5%	0.8%	0.031
Neonatal jaundice	30.2%	10.3%	0.001
Neonatal hypoglycemia	8.1%	1.0%	0.004
Average hospital stay (days)	4.1 ± 1.5	3.6 ± 1.1	0.0003
Apgar score			
1 min	7.1 ± 1.3	8.0 ± 0.3	NS
5 min	7.9 ± 0.3	8.8 ± 0.1	NS

Discussion

Women who had GDM had a higher frequency of pregnancy-associated comorbidities, as well as unfavourable outcomes for both the mother and the foetus. This was true even if the comorbidities were unrelated to the pregnancy. They had a higher risk of developing problems such as intrauterine growth restriction (IUGR), macrosomia, oligohydramnios, and polyhydramnios; however, the rate of congenital abnormalities did not differ between the two groups of women. Women with normoglycemia had a lower risk of developing problems such as macrosomia, oligohydramnios, and polyhydramnios. Women who were pregnant and had gestational diabetes had a significantly increased risk of both having their labour artificially induced and having a caesarean section performed. Babies who were delivered to mothers who suffered from GDM had an increased risk of developing newborn hypoglycemia and jaundice, both of which required treatment, and they needed to spend more time in the hospital. GDM is a condition that affects both women and their unborn children.

The average level of HbA1c in women with GDM was 6.1% between the ages of 24 and 28 weeks, while the level in women with normoglycemia was 5.3%. In a prior study that had 500

patients, Balaji et al. reported mean HbA1c values of 5.89% and 5.40% in women with GDM and normoglycemia, respectively. However, women with all trimesters were included in the study. In addition, the researchers discovered that women who had GDM had a greater risk of experiencing problems during pregnancy than women who did not have GDM. In a second recent study, Rajput et al. showed that women with GDM had mean HbA1c levels of 5.69%, whereas women with normoglycemia had mean HbA1c values of 5.35%. This finding was based on the fact that women with normoglycemia had HbA1c levels that were 5.35%. An HbA1c level of 5.64% had a sensitivity of 86.5% and a specificity of 61%, whereas a cutoff of.96% had a sensitivity of 28% with a specificity of 94%, and the ROC curve of HbA1c for diagnosing GDM had an AUC of 0.806. ROC curve of HbA1c for diagnosing GDM. In the same investigation, it was demonstrated that this is indeed the case.

According to our findings, the AUC of the ROC curve of HbA1c for the diagnosis of GDM was 0.827, which is pretty equal to the AUC that Rajput et al. reported in their earlier work. A value of 5.4% for HbA1c as the cutoff would have precluded an OGTT from being performed in about half of the pregnant women (232/400, 46.4%), but it would have missed approximately 6% of the women who had GDM. If a HbA1c cutoff value of 6.3% had been selected, almost 94% of the participants could have been spared the inconvenience of undergoing an OGTT. On the other hand, this would have resulted in the inaccurate identification of more than fifty percent of diabetic women as having normal glucose levels when they actually had GDM. As a consequence of this, it is suggested that, for the purpose of screening, a HbA1c number that is lower be used.

Some unfavourable pregnancy outcomes, such as shoulder dystocia, macrosomia, neonatal hypoglycemia, the need for neonatal resuscitation, and the duration of hospital stay, showed a correlation with HbA1c at 24–28 weeks, whereas an association of this nature could not be established with others, such as IUGR or congenital foetal mal-formations. It's possible that this is due to the fact that our study cohort had a low incidence of the events we were looking at as well as a small sample size to begin with.

The results of our study indicate that an elevated level of fasting plasma glucose was detected in 96 percent of the women who were diagnosed with GDM. This is a different example than the one that was given earlier.

HAPO study, which discovered that FPG accurately identified 52.4% of women with GDM, but the 1-h and 2-h plasma glucose post-OGTT correctly identified only 36.5% and 14% of women, respectively. In addition, it has been proven that FPG has a good sensitivity for the diagnosis of GDM at cutoffs ranging from 86 to 94 mg/dL. These ranges were chosen in order to accommodate a wide range of patients. These severances were utilised in the past at various points. 31–33 It was originally suggested that a 3-hour OGTT be performed in order to diagnose GDM; however, it has been previously established that a 2-hour OGTT is just as good, without any harmful effects on the perinatal outcome. [Citation needed] [Citation needed] [Citation needed] [Citation needed] [Citation needed] [Citation needed] [Citation 33

We gave all of the women who had GDM an OGTT as well as a HbA1c test at six weeks postpartum, and the majority of them, 84.5 percent of them, maintained within normal glucose levels. Kim et al.27 carried out research with the purpose of determining whether or not testing for postpartum HbA1c is effective. According to the findings of that other study, which was rather comparable to the one we conducted, there was a reasonable correlation between HbA1c and glucose levels. They recommended setting the threshold for HbA1c at 5.7%, which would have a sensitivity of 65% and a specificity of 68%, respectively.

Because of the extended amount of time needed for changes in HbA1c, it is often believed that HbA1c is unsuitable for the diagnosis of GDM. The reasoning behind this belief is as follows: This is because HbA1c indicates the mean plasma glucose level in the three to four months prior to the test. The reason for this is that HbA1c. Even though glycation of haemoglobin occurs over the course of the entire 120-day life span of red blood cells, it has been demonstrated that the mean plasma glucose over the course of the previous month is responsible for contributing to 50% of the final result. This is the case even though the process takes place over the course of the entire life span of red blood cells. 35 As a consequence of this, HbA1c may play a role in the screening process for gestational diabetes, particularly in the event that the cutoffs used are lower than those that are suggested for the diagnosis of diabetes mellitus in people who are not pregnant. This is particularly true in the event that the cutoffs employed are lower than those that are suggested for the diagnosis of diabetes mellitus in people who are not pregnant. Because anaemia is known to cause fluctuations in HbA1c, the fact that our study exclusively included people with normal levels of haemoglobin is one of the study's benefits. The limitation of our study is that we only had a limited number of participants to sample from.

Although HbA1c cannot replace OGTT in the diagnosis of GDM, it can be used as a screening test, and if a cutoff of 5.3% is chosen, it can eliminate the need for OGTT in approximately half of all women. In conclusion, although HbA1c cannot replace OGTT in the diagnosis of GDM, it can be used as a screening test. Validation of our findings is required in a considerably larger participant sample at this point.

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