Original Article

Accuracy of Fasting Capillary Blood Glucose by Glucometer for Screening of Gestational Diabetes Mellitus: Simplicity is the Key

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Abstract

Objective: The objective of this study is to assess the diagnostic accuracy of fasting capillary blood glucose (CBG) using glucometer for screening of Gestational Diabetes Mellitus (GDM).

Methodology: Pregnant women in their second or third trimester, who visited the laboratory for Oral Glucose Tolerance Test, were included in the study. Fasting capillary blood glucose was measured using a glucometer and simultaneous fasting venous plasma glucose levels were analyzed on fully automated chemistry analyzer. Using the American Diabetic Association (ADA) criteria, patients with fasting VPG levels>92 mg/dl were labeled as having GDM. The diagnostic accuracy of CBG was presented in terms of sensitivity, specificity, predictive values and likelihood ratios.

Results: Total number of patients were 713, out of which 33(4.62%) were diagnosed as having GDM, according to ADA criteria. Mean maternal age was 29.00+4.63 years, mean gestational age was 26.54+5.28 weeks, mean weight was 67.28+10.24 kg and mean BMI was 26.07+3.96 kg/m2. Mean fasting CBG was 89.94+7.17md/dl, mean fasting VPG was 84.06+7.32 mg/dl, mean difference between two values was 5.89+3.17mg/dl. Pearson's correlation was 0.904(p-value<0.001).Fasting CBG by glucometer had sensitivity 96.97%, specificity78.24%, positive predictive value 17.78%, negative predictive value 99.81%, positive likelihood ratio 4.46 and negative likelihood ratio 0.04. Diagnostic accuracy of fasting CBG by glucometer was 79.10%.

Conclusion: Fasting CBG is a simple, cost effective, rapid and convenient method. It can be recommended for screening of GDM in pregnant women especially at health care centers where automated analyzers are not available.

Keywords: GDM, Screening, Diagnosis, fasting capillary blood glucose.

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Introduction

Pregnancy is a physiological state in which a woman's metabolic systems go through immense changes as a result of hormonal extravaganza. During pregnancy, many chronic conditions may worsen or some new metabolic complications may arise. Gestational Diabetes Mellitus (GDM) is the most common metabolic disorder recognized in pregnant women. It is defined as "any degree of hyperglycemia that is recognized for the first time during pregnancy".[1]

Early and correct identification of GDM cannot be over emphasized as GDM is associated with a multitude of maternal and fetal complications including hypertension,[2] pre-eclampsia,[3] caesarian section,[4] type 2 diabetes,[5] preterm labor in mother,[6] macrosmia,[7] shoulder dystosia,[8] hyperbilirubinemia,[6] neonatal hypoglycemia,[9] respiratory distress syndrome,[10] congenital malformations , obesity and increased risk of developing diabetes or prediabetes in children born

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from women with GDM.[6]

Increasing numbers of GDM patients are being reported every year especially in Asian women.[11] Fatima S et al recently reported the frequency of GDM as 26.3% in Pakistan.[12] Other studies have shown a prevalence varying between 3.3-8%.[13] Despite the high frequency and widespread nature of this potentially treatable condition considerable controversy still exists when it comes to screening and diagnosis protocols of GDM. World Health Organization (WHO) recommends a two-step procedure for the diagnosis of GDM. With a positive oral glucose challenge test (OGCT),2 h glucose tolerance test with 75 g is recommended. A cut-off value >140 mg/dl at 2 h is taken as diagnostic for GDM.[14] American Diabetes Association (ADA) and American College of Obstetrician & Gynecologist(ACOG) recommend a risk factor based screening for all women. A Glucose challenge Test(GCT) is done with 50 gm glucose and if GCT is found to be positive it is followed by a 75g moral glucose tolerance test (OGTT)in two step approach. One step approach calls for only a 75 OGTT.[13]

According to Carpenter and Coustan criteria women are screened using 3-h 100 g OGTT and two cut-off values are required to diagnose GDM. Diabetes in a pregnancy study group of India (DIPSI), recommends performing 75 g OGTT in non-fasting state and a single 2 h value of >140 mg/dl is taken as diagnostic of GDM.[6]

All these protocols have their own pros and cons and need multiple venous blood samples. Nausea and vomiting are commonly observed during these procedures because of ingestion of a large amount of glucose on empty stomach.[13] High cost, multiple venous samplings, complex procedure, specialized training, and advanced glucose measuring techniques are among other notable pitfalls especially in resource depleted regions like ours. The utility of CBG has been studied and CBG has shown promising results when compared to VPG when used for screening and diagnosis of GDM.[15]

In this study, we set out to determine the diagnostic accuracy of fasting CBG for detection of abnormal glycemic control as defined by VPG levels using ADA criteria[16] in Pakistani pregnant females.

Methodology

This cross sectional analytical was conducted from 5th February 2020 to 6th December 2020 at National Medical Center Karachi. All pregnant women in the second and third trimesters, who came in with the request of 75gm Oral Glucose Tolerance Test (OGTT) were recruited for the study. Permission from the Ethical Committee of the Hospital was taken. Informed consent was obtained and a questionnaire including patient's data regarding age, total body weight, height, body mass index, weeks of gestation, parity, history of miscarriage/abortion, history of GDM, history of large baby in a previous pregnancy and family history of diabetes mellitus was filled by the patient. Data from the forms was entered in especially designed excel sheet and stored for further analysis. Women with already diagnosed diabetes mellitus, chronic liver disease (hepatitis B &C), chronic kidney disease or who did not give consent were excluded from the study.

Simultaneous sampling was done for fasting CBG (finger prick using new lancet for each patient) and VPG (venous blood sample in grey top vaccutainer) before giving 75 gm oral glucose to the patient. Fasting CPG was measured on the spot using a hand held portable glucometer (On Call EZ II) and a sample in the grey top was sent to the laboratory. Fasting VPG levels were analyzed on Roche c501 fully automated chemistry analyzer using hexokinase method. Internal quality control, calibration and maintenance were done according to manufacturer's recommendations for both the assays.

Using the American Diabetic Association (ADA) criteria patients with fasting VPG levels$\geq$92 mg/dl were labeled as Gestational Diabetes Mellitus. Data for age, BMI, gestational week, fasting CBG, fasting VPG, difference between CBG and VPG was presented as mean$\pm$SD. Chi-square test was applied to find out relationship between age, BMI, parity, and various other variables of interest and GDM. P-value <0.05 was taken as statistically significant. Pearson's correlation coefficient value was calculated to assess the linear relationship between CBG and VPG results. P value <0.01 was taken as significant. Linear regression plot was made for method comparison. Diagnostic accuracy of CBG was presented in terms of sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). All analyses were performed on SPSS version 22.

Results

Total number of patients were 713, out of which 33(4.62%) were diagnosed as having GDM (Fasting VPG >92 gm/dl), while 680 (95.37 %) were having normal glycemic control according to ADA criteria.

Mean maternal age was 29.00+4.63 years, mean gestational age was 26.54+5.28 weeks, mean weight was 67.28+10.24 kg and mean BMI was 26.07+3.96 kg/m2. Mean fasting CBG was 89.94+7.17md/dl, mean fasting VPG was 84.06+7.32 mg/dl, and mean the difference between the two values was 5.89+3.17mg/dl.

A statistically significant positive correlation was noted between, history of GDM in a previous pregnancy, history of large baby and GDM in the current pregnancy. However age, parity, history of miscarriage and family history of diabetes were not found to be significantly associated when using ADA diagnostic criteria, as shown in table I

Upon analysis of fasting CBG for diagnosis of GDM (with fasting VPG >92gm/dl as gold standard), 32 patients were found to be true positives and only 1 case was false negative as shown in table II.

Table I: Association between age, BMI, parity, history of DM, GDM, miscarriage, large baby and GDM in current pregnancy. VPG, Venous Plasma Glucose; BMI, Body Mass Index; GDM, Gestational Diabetes Mellitus; DM, Diabetes Mellitus.

Variables	Gestational Diabetes Mellitus Fasting VPG ≥92 md/dl	Normoglycemia Fasting VPG< 92 md/dl	p-Value
	N(33)	N(680)	
Age			
<26 Years	7(3.2%)	215(96.8%)	0.207
>26 Years	26(5.3%)	465(94.7%)	
BMI			
<25	6(1.8%)	320(98.2%)	**0.001***
>25	27(7.0%)	360(93.0%)	
Parity			
Nulliparous	10(3.4%)	283(96.6%)	0.197
Multiparous	23(5.5%)	397(94.5%)	
History of GDM			
Yes	27(96.4%)	1(3.6%)	**<0.001***
No	6(0.9%)	679(99.1%)	
Family history of DM			
Yes	11(4.8%)	216(95.2%)	0.850
No	22(4.5%)	462(95.5%)	
History of Miscarriage			
Yes	6(7.9%)	70(92.1%)	0.152
No	27(4.2%)	610(95.8%)	
History of Large Baby			
Yes	17(81.0%)	4(19.0%)	**<0.001***
No	16(2.3%)	676(97.7%)	

The Pearson's correlation coefficient value was r= 0.904, this proves significant positive correlation between results of CBG and VPG. Fasting CBG had good sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV). Positive likelihood ratio was 4.46, while negative likelihood ratio was 0.04 and the diagnostic accuracy of fasting CBG was 79.10 %, as depicted in table III. Linear regression was used to establish a relationship between VPG and CBG values (keeping VPG as the dependent variable and CBG as the independent variable) as shown in Figure 1.

Table II: Number of correctly diagnosed cases by fasting CBG. VPG, Venous Plasma Glucose; CBG, Capillary Blood Glucose; TP, True Positive; FP, False Positive; TN, True Negative; FN, False Negative

	Fasting VPG by Cobas c501		
Fasting CBG by Glucometer	GDM	Normoglycemia	Total
GDM	32(TP)	148(FP)	180(25.25%)
Normoglycemia	01(FN)	532(TN)	533(74.75%)
Total	33	680	713(100%)

Table III: Diagnostic accuracy of fasting CBG by glucometer in the diagnosis of GDM taking fasting venous plasma glucose (VPG) by Cobas c501 as the golden standard.

Test	Value	95%CI
Sensitivity	96.97%	84.24% to 99.92%
Specificity	78.24%	74.94% to 81.28%
PPV	17.78%	15.63% to 20.15%
NPV	99.81%	98.72% to 99.97%
Diagnostic accuracy	79.10%	75.93% to 82.03%

Sensitivity=TP/(TP+FN); Specificity = TN/(TN+FP); PPV=TP/(TP+FP); NPV = TN/(TN+FN); Likelihood ratio positive = sensitivity/(100 −specificity); Likelihood ratio negative = (100 − sensitivity)/specificity; Diagnostic accuracy = (TP+TN)/(TP+TN+FP+FN).

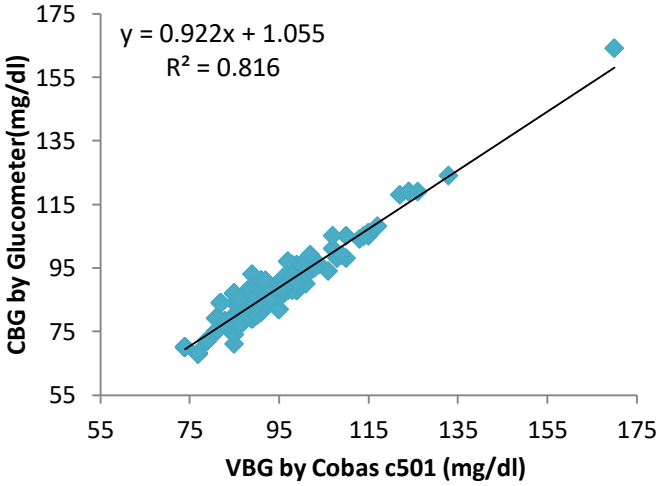

Figure 1. Linear regression of CBG (Capillary Blood Glucose) versus VPG (Venous Plasma Glucose) in mg/dl.

Discussion

Gestational diabetes mellitus is a fairly common occurrence in pregnancies in Pakistan.[13] GDM can result in various maternal and fetal complications. All the adverse effects of GDM on the mother and baby can be easily prevented by a timely and prompt diagnosis of this condition. Although much work has been already done by several endocrine societies for the development of guidelines for screening and diagnosis of pregnant women still no worldwide consensus has been achieved. Most of the guidelines are issued by societies working in the developed world and they recommend an oral glucose tolerance test (OGTT) with 100 gm or 75 gm glucose. This OGTT procedure involves multiple samplings, long waiting time, skilled staff, and modern laboratory facilities making it very impractical for universal screening purposes in recourse limited countries like Pakistan.

The mean gestational age of our study population was 26.54±5.28 weeks, mean weight was 67.28+10.24 kg, and mean BMI was 26.07±3.96 kg/m2, roughly similar results have been reposted by Hossain N et al.[13] A statistically significant positive correlation was noted between BMI, history of GDM in previous pregnancy and history of a large baby. Association between increased BMI and GDM has already been well established. Increased BMI is a potentially modifiable factor that can lead to a decreased risk for GDM in future pregnancies. However, age, parity, history of miscarriage, and family history of diabetes were not found to be significant. Another study done in Pakistan identified a positive correlation between advancing age, BMI, and history of diabetes mellitus in first degree relatives.[17] Contarary to findings of this study no association was found with a history of the large baby in another research.[18]

We noted that out of the 33 cases of GDM (diagnosed by fasting VPG≥92mg/dl) only one case was labeled false negative by CBG levels measured by glucometer. This means that chances of missing any GDM case during screening by this method are very low. Out of the 713 patients, 532(74.6%) were correctly identified as negative for GDM. Fasting CBG by glucometer had sensitivity 96.97% (CI=84.24-99.92), specificity 78.24% (CI=74.94-81.28), positive predictive value (PPV) 17.78% (CI=15.63-20.15), negative predictive value (NPV) as high as 99.81% (CI=98.72-99.97) and positive likelihood ratio 4.46, while negative likelihood ratio was 0.04 and diagnostic accuracy of fasting CBG by glucometer was 79.10 %. This implies that fasting CBG is a very sensitive but moderately specific test. Upon screening 180(25.25%) patients had fasting CBG by glucometer ≥ 92mg/dl and will be required to undergo 75 gm OGTT for definitive diagnosis of GDM. This screening technique correctly identified 532(78.24%) as negative for GDM, so these patients do not need to take 75 gm OGTT for GDM diagnosis saving a lot of time, effort, and money.

The correlation of CBG and VPG values was high,with Pearson's correlation value r=0.904, which tells us about the positive linear relationship between the two values. Another study done byIgnell C et al has reported r=0.93, which validates our results.[19] However this linear relationship is dependent on precision of measurements and range of data. To compare the two methods, we carried out linear regression analysis. R^2 = 0.816, pointing towards the fact that fasting CBG and fasting VPG can be used interchangeably for screening of GDM.Similar findings have been reported but for 2 hours post 75gm glucose.[20]

There are some limitations of this study. Firstly only one type and brand of glucometer (On Call EZ II) was used, so the results of this research should be carefully applied for further studies. Also, we conducted our study in one center so the prevalence of GDM may not be same in the community at large. These results warrant population based studies for future.

Conclusion

A single fasting CBG measured by glucometer can prove to be a useful tool for GDM screening in developing countries like Pakistan. Since this method requires only 1 drop of blood, minimizes patient discomfort, needs minimum technical expertise and is also cost effective. However clinical judgment should always be given prime importance in making the final diagnosis

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