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The Accuracy of Capillary Whole Blood Glucose Versus Venous Plasma Glucose in the Diagnosis of Gestational Diabetes Mellitus in Egyptian Women

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Abstract

Objective: To check the accuracy of measuring Venous Plasma Glucose (VPG) and Capillary Glucose (CBG) in Gestational Diabetes (GD) among Egyptian women, adopting the standards of Diabetes in Pregnancy Study Group India (DIPSI).

Design: Prospective study.

Setting: Tanta University Hospital.

Methods: It was a prospective pilot study conducted on five hundred pregnant ladies with risk factors for glucose intolerance, and pregnant in second and third trimesters. Ladies recruited between May 2018 to May 2020. Seventy-five gram oral glucose was given, regardless of last meal; venous and capillary blood samples were collected at two. Correlation between VPG and CBG, sensitivity, specificity, and predictive values of either for abnormal glycemic profile (G.D. or D.M.) was assessed.

Result: The mean age of the participants was 24.89 ± 4.7 years, and also, the mean age (G.A.) was 25.77 ± 1.37 weeks. The mean BMI for the Normoglycemic group and, therefore, the diabetic group was 27.62 and 27.62, respectively. Only 55 of 500 cases were diagnosed as GDM in line with the DIPSI criteria, and 445 were Normoglycemic. The mean BMI for the Normoglycemic group and also the diabetic group was 27.62 and 27.62, respectively. We found a statistically significant direct correlation between CBG and VPG levels. The world under the curve by using the Receiver Operating Characteristic analysis was 0.995, which shows the high prediction power with 95% CI. The CBG cut point of 140 mg/dl provides the optimal sensitivity and specificity of 90.91% and 96.63%, respectively. The positive predictive value was 76.92%, and Negative predictive value was 98.85% at the same cut-off. There was an agreement between CBG and VPG where kappa value (K) is 0.803.

Conclusion: Measuring capillary blood sugar is an appropriate and cheap test for the diagnosis of gestational diabetes in developing countries.

Keywords: Gestational diabetes mellitus; Capillary blood glucose; Venous blood glucose; Diabetes in Pregnancy Study Group India (DIPSI)

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Introduction

Gestational diabetes (GDM) is currently defined as any degree of glucose intolerance with onset or first recognition during the current pregnancy [1-4]. GDM affects 1%-2% of all pregnancies [1]. Gestational diabetes (G.D.) has related to adverse pregnancy outcomes on mother and foetus. Therefore, accurate early screening could reduce complications or prevent GDM at once with subsequent improvement of pregnancy outcome [2]. A variety of screening procedures and diagnostic criteria followed in numerous countries like American Diabetes Association (ADA), World Health Organization (WHO), Canadian Diabetes Association (CDA), National Diabetes Data Group (NDDG) and Australian criteria [3]. So, universal screening appears to be

the foremost reliable and desired method for detecting GDM [4]. The International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria include a universal 75 grams Oral Glucose Tolerance Test (OGTT) during screening between 24 and 28 weeks gestation and also the diagnosis of GDM to be supported a glucose level exceeding or equaling anybody of the subsequent three thresholds: 92 mg/dL for fasting plasma glucose (FPG), 180 mg/dL for the one-hour postprandial plasma glucose, and 153 mg/dL for the two-hour postprandial plasma glucose [5]. World Health Organization (WHO) also recommends a 2 step procedure for the diagnosis of GDM, with a positive OGTT, 2 hours glucose tolerance test with 75 grams suggested. A glucose level below 7.8 mmol/L (140 mg/dL) is average, whereas higher levels are diagnostic for GDM. Diabetes in a pregnancy study group of India (DIPSI), recommends a "one-step" screening protocol for GDM using 75 grams OGTT in non-fasting state one to two hours value of >140 mg/dl taken as diagnostic of GDM [6]. Venous sampling is widely used as a laboratory technique for the diagnosis of D.M. However, using venous sampling on multiple occasions in asset limiting settings is not acceptable from the economic point of view [7]. Therefore, within the current study, we are going to determine if capillary blood sampling, which is convenient enough to require the place of venous sampling or not.

Patients and Methods

This study is a prospective cohort study carried out at the Department of Obstetrics and Gynaecology, Tanta University Hospitals. The duration of the study was two years, starting from 1st of May 2018. The research was done on 500 pregnant ladies with risk factors for glucose intolerance; they were enrolled while seeking antenatal care at the outpatient clinic according to the following criteria:

Inclusion criteria

Single pregnancy, age of the female between 18 and 35 years, In the 2nd or 3rd trimester, obesity (BMI>25 kg/m^2), history of unexplained intrauterine fetal death, history of macrosomia in a previous pregnancy, history of gestational diabetes, polyhydramnios with unidentifiable cause as open spina bifida or esophageal atresia, history of Polycystic ovary syndrome, and family history of diabetes.

Exclusion criteria

Well-established diabetes, chronic liver disease, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Multiple pregnancies. After written consent, the study population subjected to the following: A complete history taking done for each case, including age, weight, height and obstetric history (mainly last menstrual period, number of previous pregnancies, history of unexplained abortions, stillbirths, history of preterm labour and history of macrosomia. History of chronic diseases as hepatic and renal diseases and family history of diabetes mellitus also are taken into consideration. Seventy-five grams of glucose dissolved in 100 ml of water given to the participants in a non-fasting state irrespective of the last meal. After 2 hours, Capillary Whole Blood Glucose (CWBG) and Venous Plasma Glucose (VPG) were measured simultaneously.

Capillary blood glucose (CBG) levels are measured using Accu-Chek Active glucometer. Participants asked to wash their hands with tap water and neutral soap-a capillary sample obtained through fingertips. Blood dropped systematically on the test strips of glucometer, and the findings were recorded.

Concomitantly, VPG levels were measured by an oxidase-peroxidase method using the analyzer. A professional nurse collected venous whole blood samples (1.5 ml) from the ante capital area in the right or left forearm (according to the non-dominant arm). Blood samples were drawn into 4 mL of sodium fluoride/oxalate tubes. The tubes were then appropriately labelled and stored at room temperature, transported to the laboratory for plasma glucose measurement within 120 minutes. In the laboratory, samples were centrifuged, and venous plasma glucose obtained using the oxidase- peroxidase method for all participants. Women with venous plasma glucose levels between 140 mg/dl and 200 mg/dl diagnosed as gestational diabetes. Higher levels of VPG are excluded as they are considered cases of established diabetes according to DIPSI criteria [7].

Statistical analysis of the data

Data was fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data described using numbers and percentages. The Kolmogorov-Smirnov test was used to verify the normality of distribution. Quantitative data defined using range (minimum and maximum), mean, standard deviation, median, and Interquartile Range (IQR). The significance of the obtained results judged at the 5% level. The used tests were: Spearman coefficient, Sensitivity, Specificity, Receiver Operating Characteristic Curve (ROC), Positive Predictive Value (PPV), Negative Predictive Value (NPV), Odd Ratio (OR) and Kappa (κ) test.

Follow up

Patients proved to be diabetic were transferred to the diabetes clinic and submitted to antenatal care, as high-risk cases.

Results

In the existing study, 500 pregnant females were recruited; 55 of them were diagnosed as Gestational Diabetes Mellitus (GDM) according to the criteria of Diabetes In A Pregnancy Study Group In India (DIPSI), where Venous Plasma Glucose (VPG) ≥ 140 mg\dl) and considered as GDM group, and 445 were normoglycemic (VPG was <140 mg\dl). The results of the current study are shown in ten tables and three figures. The pie chart in **Figure 1**. Shows that 11% of the participants were diagnosed with gestational diabetes.

Table 1 represenfts fthaft fthe mean age off fthe parficfipanfts was 24.89 ± 4.7 years, and the mean gestational age (G.A.) was 25.77 ± 1.37 weeks. **Table 2** portrays that the mean value of CBG for participants was 105.30 ± 26.28 mg/L and the p-value is statistically significant. **Table 3** shows that the values of the weight and height from which body mass index (BMI) was

calculated and showed statistical significance p ≤ 0.01. The mean BMI for the normoglycemic group and the diabetic group was 27.62 and 27.62 respectively. **Table 4** explains a comparison between the two groups according to gravidity; 193 of the participants were primigravida constituting 38.6% of total participants, 178 were normoglycemic, and 15 diagnosed as G.D. According to the p-value, gravidity had no statistical significance where p-value=0.067 as it is statistically significant at p ≤ 0.05.

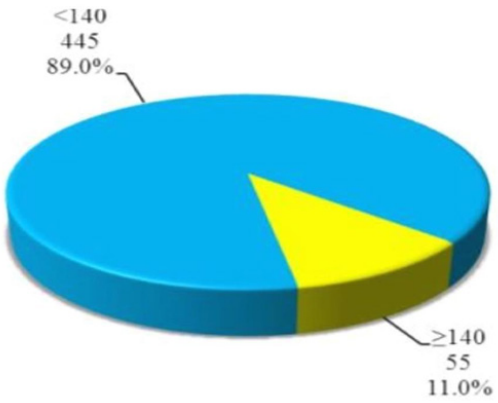

Figure 1: Distribution of the studied cases, according to VPG (n=500).

Venous plasma glucose (VPG)	No.	%
<140	445	89
≥ 140	55	11
Min-Max	61-175	
Mean ± SD	96.69 ± 24.67	
Median (IQR)	89.50(79-103)	

Table 1: Distribution of the studied cases, according to VPG (n=500).

	Total (N=500)		VPG				p
			<140 (N=445)	≥ 140 (N=55)	<140	<140	
	No.	%	No.	%	No.	%	
Age							
<26	304	60.8	283	63.6	21	38.2	<0. 001*
≥ 26	196	39.2	162	36.4	34	61.8	
Min-Max	18.0-36.0		18.0-36.0		19.0-36.0		0. 002*
Mean ± SD	24.89 ± 4.70		24.68 ± 4.70		26.71 ± 4.28		
Median (IQR)	24.0(21.0-27.0)		23.0(21.0-27.0)		26.0(24.0-29.50)		
Gestational Age							
Min- Max	24.0-29.0		24.0-29.0		24.0-28.0		0.079
Mean ± SD.	25.77 ± 1.37		25.73 ± 1.37		26.07 ± 1.39		
Median (IQR)	26.0(25.0-27.0)		26.0(25.0-27.0)		26.0(25.0-27.0)		

Table 2: Comparison between the two studied groups according to demographic data.

	VPG			
CBG	Total (n=500)	<140 (n=445)	≥ 140 (n=55)	p
Min-Max	67.0-181.0	67.0-145.0	138.0-181.0	<0. 001*
Mean ± SD	105.30 ± 26.28	98.07 ± 16.81	163.75 ± 12.29	<0. 001*
Median (IQR)	97 (87-115)	94 (86-111)	166 (158-172)	

Table 3: Comparison between the two studied groups according to Capillary Blood Glucose (CBG).

Measures	VPG			p
	Total (N=500)	<140 (N=445)	≥ 140 (N=55)	
Weight				0. 039*
Min-Max	60-99	60-99	60-95	0.068
Mean ± SD	73.4 ± 7.99	73.17 ± 7.69	75.31 ± 9.97	
Median (IQR)	73 (68-78)	73 (68-78)	79 (67.5-84)	
Height				0. 003*
Min-Max	1.5-1.74	1.5-1.74	1.52-1.7	0. 003*
Mean ± S.D	1.63 ± 0.06	1.63 ± 0.06	1.61 ± 0.06	
Median (IQR)	1.63(1.6-1.7)	1.64(1.6-1.7)	1.62(1.6-1.7)	
BMI				<0. 001*
Min- Max.	25-37	25-37	26-34	<0. 001*
Min- Max.	25-37	25-37	26-34	
Min- Max.	25-37	25-37	26-34	

Table 4: Comparison between the BMI, weight, and height of the patients.

Table 5 demonstrates the incidence of some obstetric history parameters and family history of D.M. among the normoglycemic and GDM groups where the history of PTL constituted 7.2%, totally, 6.3% in normoglycemic group and 14.5% in the gestational diabetic group. The history of stillbirth was 8.8%, totally, 8.3% in the normoglycemic group and 12.7% in the GDM group. History of unexplained abortion was 11.6%, totally, 12.1% in normoglycemic, and 7.3% in GDM. The history of GDM was 2.8%, totally, 0.7% normoglycemic, and 20% GDM. History of macrosomia was 2.6%, totally, 1.6% in the normoglycemic group, and 10.9% in the GDM group. The family history of D.M. was 20.2%, totally, 17.5% in the normoglycemic group, and 41.8% in the GDM group. History of PTL, stillbirth, GDM, and family history of D.M. has a strong association with incidence of GDM, as shown in **Table 6** where p values of each item were less than 0.05, which is statistically significant. All significant variables were considered for multivariate analysis. The final multivariate model shows that, i.e., Age, BMI, positive history of macrosomia, stillbirth history of GDM, PTL, and family history of diabetes are highly significant and strongly associated with VPG ≥ 140 where (p<0.05). The odds ratio with a 95% confidence interval is illustrated in the **Tables 7 and 8** shows a sftafisficaflfly sfignfificanft positive correlation between CBG and VPG levels using DIPSI crfifterfia (Spearman coeficfienft (r) fis 0.992, (P<0.001) **Figure 2** shows the agreement between VPG and CBG with Spearman coeficfienft 0.992. **Figure 3**, displays the area under the curve by using the Receiver Operating Characteristic analysis (ROC) was 0.995, which shows the high prediction power with 95% CI (0.991-0.999). **Tables 9 and 10** exhibit the CBG cut point of 140 mg/dl provides the optimal sensitivity and specificity of 90.91% and 96.63%, respectively. Positive predictive value (PPV) was 76.92%, and negative predictive value (NPV) was 98.85% at the same cut-off. There was excellent agreement between CBG and VPG where kappa value (K) is 0.803.

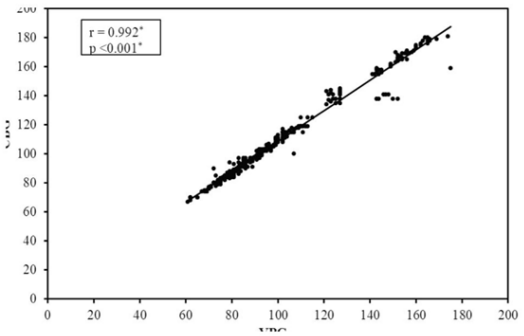

Figure 2: Correlation between VPG and CBG.

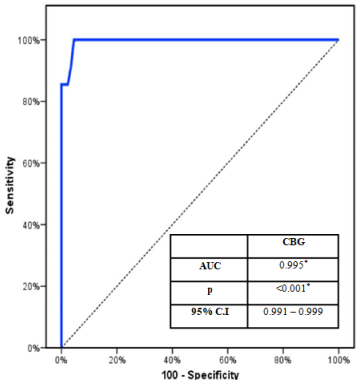

Figure 3: ROC curve for CBG to predict VPG cases (≥ 140).

	VPG						p
	Total (N=500)		<140 (n=445)		≥ 140 (N=55)		
	No.	%	No.	%	No.	%	
Gravidity							
Primigravidas	193	38.6	178	40	15	27.3	0.067
Multigravidas	307	61.4	267	60	40	72.7	
Parity							
0	217	43.4	199	44.7	18	32.7	0.09
≥ 1	283	56.6	246	55.3	37	67.3	

Table 5: Comparison between the two studied groups according to gravidity and parity.

	VPG						p
	Total (N=500)		<140 (n=445)		≥ 140 (N=55)		
	No.	%	No.	%	No.	%	
Preterm labour	36	7.2	28	6.3	8	14.5	p=0.046*
Stillbirth	13	2.6	9	2	4	7.3	P=0.031*
Unexplained miscarriage	58	11.6	54	12.1	4	7.3	0.288
Family history diabetes	101	20.2	78	17.5	23	41.8	<0.001*
History of GDM	14	2.8	3	0.7	11	20	p<0.001*
History of macrosomia	13	2.6	7	1.6	6	10.9	p=0.001*

Table 6: Comparison between the two studied groups according to obstetric history parameters and family history of diabetes mellitus.

	VPG					
	<140 (n=445)		≥ 140 (n=55)		p	OR(95%C.I)
	No.	%	No.	%		
Age						
<26	283	63.6	21	38.2		
≥26	162	36.4	34	61.8	<0.001*	2.828(1.588 - 5.038)
BMI						
<30	397	89.2	35	63.6		
≥30	48	10.8	20	36.4	<0.001*	4.726(2.528 - 8.836)
History of GDM						
No	442	99.3	44	80		
Yes	3	0.7	11	20	<0.001*	36.833(9.902 - 137.01)
History of macrosomia						
No	438	98.4	49	89.1		
Yes	7	1.6	6	10.9	<0.001*	7.662(2.476 - 23.711)
Stillbirth						
No	436	98	51	92.7		
Yes	9	2	4	7.3	0.031*	3.800(1.130 - 12.780)
Family hist diabetes						
No	367	82.5	32	58.2		
Yes	78	17.5	23	41.8	<0.001*	3.382(1.877 - 6.094)
PTL						
No	417	93.7	47	85.5		
Yes	28	6.3	8	14.5	0.046*	2.535(1.093 - 5.881)
OR: Odds ratio; CI: confidence interval; P: p-value for comparison between the studied groups						

Table 7: Multivariate logistic regression adjusted for age, BMI, history of macrosomia, stillbirth, history of GDM, and family history of D.M.

	r_s	p
VPG versus CBG	0. 992*	<0. 001*

Table 8: Correlation between VPG and CBG (n = 500).

	cut off	sensitivity	specificity	PPV	NPV
CBG	>140	90.91	96.63	76.92	98.85

Table 9: Sensitivity and specificity of CBG in the prediction of G.D.

	VPG								
CBG	<140 (n=445)		≥ 140 (n=55)		sensitivity	specificity	PPV	NPV	
	No.	%	No.	%					
Negative (≤ 140)	430	96.6	5	9.1	90.91	96.63	76.92	98.85	96
Positive (>140)	15	3.4	50	90.9					
κ(p)	0.811 (<0.001*) very								
	Good agreement								

Table 10: Accuracy of CBG in the diagnosis of GD.

Discussion

Criteria for diagnosis of gestational diabetes (GDM) have involved nonstop discussion [8], and therefore the optimal approaches to diagnose gestational D.M. (GDM) remain contested [9]. To most of our knowledge, this the first study in Egypt using the criteria of diabetes within the pregnancy study group of India (DIPSI).

We used the DIPSI criteria [7] for its simplicity and thanks to the convergence of societal conditions between Egypt and India.

The mean age of the participants was 24.73 ± 4.69 years. Mean BMI for the Normoglycaemic group and GDM group was 27.62 and 27.62, respectively. Simultaneous two samples were taken for CWBG and VPG measurements from each participant. 11% of the participants (55) diagnosed as G.D., and also, the rest were normoglycemic (445). A statistically significant direct correlation was noted between CWBG and VPG levels using DIPSI criteria (correlation coefficient was 0.992, P<0.001).

Sensitivity and specificity were 90.91% and 96.63%, respectively. Positive predictive value (PPV) was 76.92%, and negative predictive value (NPV) was 98.85% at the same cut-off. There was excellent agreement between CBG and VPG where kappa value was 0.803. The world under the curve using the Receiver operator characteristic analysis (ROC) was 0.995 with 95% CI (0.991-0.999) Bland and Altman graph showing the agreement between VPG and CWBG with spearman coefficient 0.992. Dacus in their study on the topic with GDM, found the sensitivity of 82% and specificity of 98% of CBG in comparison with VPG [10]. Moreover, we studied the role of risk factors precipitating GDM. We concluded that; age, BMI, positive history of macrosomia, history of GDM, preterm labor PTL, stillbirth, and case history of diabetes are highly significant and strongly related to VPG ≥ 140 mg/dl where (p<0.05 altogether of those items). Other factors are insignificant because of the previous history of unexplained abortion and maternal age. Hossain and associate found that the mean body mass index of the ladies in with GDM was 26 kg/m^2 in a very study from Pakistan Northern Province, women with GDM were also found to possess a mean body index of 28 (kg/m^2). Association between increased body mass index and gestational D.M. was well established [11]. Kiani and collaborates found that the mean BMI in cases of GDM was 27.53, which is located at the overweight range [12]. Irving and co-workers reported a positive case history of D.M. in 23% of their studied cases [13].

The study of Priya is in agreement with our research. They studied diabetes (D.M.) diagnosis in 407 subjects ≥ 20 years old (54.1% male) center in Chennai, India; (This study is on D.M. generally not G.D.). Simultaneous measurements of CWBG and VPG performed, both within the fasting state and a couple of hours after a 75 grams glucose load (2 Hrs. post glucose load). Impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) were defined using the American Diabetes Association and the World Health Organization criteria. They stated that CWBG could be a feasible alternative for screening diabetes and IGT in epidemiological studies in developing countries where obtaining venous samples could also be stressful [14].

Balaji and associates studied GDM in pregnant women within the trimester. The participants got 75 grams oral glucose within the fasting state. After 2 hours, CBG was measured by finger-prick employing a one-touch select simple glucometer. Blood was drawn to estimate VPG within the laboratory by glucose oxidase peroxidase (GOD-POD) method. The diagnosis of GDM was supported by 2 hours of plasma glucose ≥ 7.8 mmol/l, which corresponds to ≥ 140 mg/dl. Among 500 pregnant women, 32 (6.4%) diagnosed as GDM in their first visit. This had a sensitivity of 93.8% and specificity of 97.4% with a false positive and false negative of two.6% and 6.2%, respectively. These values trust our study in sensitivity, specificity, PPV, NPV mentioned before within the results. The realm under the receiver operating characteristic function of CBG was 0.993. CBG value at 2 hours plasma glucose ≥ 7.8 mmol/l could also be recommended for the diagnosis of GDM in healthcare centres where laboratory technology is not available [15]. Also, Husain and collaborates studied 1030 pregnant women. The mean age of participants was 25.8 ± 5.2 years, mean age was 28.9 ± 4.4 weeks, and therefore the mean body mass index was 25.8 ± 5.1 kg/m^2. By using the DIPSI criteria (VPG ≥ 140 mg/dl),78 (7.6%) women diagnosed as having G.D. Out of 78 G.D., 64 (6.2%) had VPG 140-200 mg/dl and 14 (1.4%) had VPG>200 mg/dl; those above 200 mg\dl considered as established diabetes; this section excluded from our study from the beginning. Statistically significant correlational statistics noted between CBG and VPG levels following DIPSI criteria [7].

Bland and Altman's graph **Figure 2** shows an agreement between VPG and CBG. CBG cut point of 140 mg/dl provides the optimum sensitivity and specificity of 94.87% (CI: 87-98.3) and 79.1% (CI: 78.4-79.4). PPV was 27.1%, and NPV was 99.4% at the same cut-off. The world under the curve by using the Receiver operator characteristic analysis was 90.3%. The ultimate multivariate model shows the highly significant, i.e., age, positive history of macrosomia, and case history of diabetes are strongly related to VPG (p<0.05). All the results were in agreement with our study apart from PPV, which was higher in our review, 76.92%. [16]

Chudasama and colleagues in their study supported the "National Guidelines for Diagnosis and Management of GDM". Their study compared the glucose level estimated by capillary testing with a glucometer and venous glucose by glucose oxidase test 2 hours after ingestion 75 g of anhydrous glucose dissolving in 200-250 ml of water. GDM found in 20.4% of pregnant women with capillary testing done by glucometer compare to 11.5% with blood testing. Intermediate agreement (Kappa=0.42) was found between two methods with sensitivity of 70.7%, specificity of 86.1%, PPV 39.7%, and NPV 95.8%. This study showed excellent agreement between CBG and VPG and having higher sensitivity and PPV; 90.91% and 76.92% [17]. Pariente and partners studied the accuracy and reliability of three glucose meters that are currently employed in a medical aid center. A sample of blood and a drop of capillary blood obtained from 59 participants. The decline was analyzed in 3 glucose meters: 2 Freestyle optimum (OP1 and OP2), and one Accu-Chek Aviva. The new American Diabetes Association standard of a complete error of ± 5% was applied. Differences in mean ± standard deviation (mg/dl) and therefore the systematic error were 5.8 ± 7 and 5.8% (OP1); 6.2 ± 8 and 5.9% (OP2); 8.3 ± 8 and 6.3% (Accu-Chek). The OP1/OP2 pair showed the best reliability level, with an intraclass correlation coefficient=0.97, bias=-0.4 mg/dL. They concluded that the best accuracy and safety standards were observed in high glucose ranges (plasma glucose ≥ 126 mg/dl). Despite their clinically acceptable mean difference compared to the plasma glucose, the three glucose meters did not fulfill the present ADA standard [18-21].

Conclusion

In the contemporary study, we noticed that the prevalence of gestational diabetes among our high-risk pregnant women was 11%. Baptiste-Roberts reported that the prevalence of gestational diabetes was 7% among the population. Behboudi Gandevani found that the pooled overall prevalence of GDM within the diagnostic threshold employed in IADPSG criteria was 10.6%. Lee and colleagues reported that the pooled prevalence of GDM in Asia was 11.5%. Lastly, we concluded that measuring capillary blood glucose is an appropriate and cheap test for gestational diabetes diagnosis in developing countries.

Conflict of interests

The authors have no conflict of interest with anybody.

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