ORIGINAL RESEARCH ARTICLE

Comparing the Glucose Values by Glucometer and Laboratory Methods in the Diagnosis of Gestational Diabetes Mellitus: A Hospital Based Study.

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Abstract:
Glucometer technology in is an easily operable and more acceptable method. We aim to compare the Glucose values determined by glucometer and laboratory method in the diagnosis of Gestational Diabetes Mellitus (GDM) so that we can recommend this more acceptable method to diagnose GDM. A total of 182 pregnant women are tested for GDM by Oral Glucose Tolerance Test (OGTT) with a single step procedure. Both Venous and capillary blood are tested for glucose levels at 2 hours after 75g Glucose load. The glucometer and laboratory results are analysed by various method comparisons to establish the analytical performance of capillary glucose values to diagnose GDM, on par with laboratory reference method. Out of 182 women tested, all four GDM cases were detected by the glucometer, giving 100% sensitivity to glucometer method and two subjects were false positive with comparison to laboratory estimation of glucose, thus 98.8% specificity was achieved, the false-positive rate (FPR) is as low as 1.2 %, and the false negative rate (FNR) is zero (area under curve 0.994). Method comparison studies too proved good agreement between glucometry and laboratory analysis. In the context of worrisome worldwide increases in obesity and diabetes rates and tiresome conventional OGTT procedure, this single step approach and that too with a single finger prick capillary blood drop and estimation of glucose with instant results appears to be a promising method in the diagnosis and management of GDM and diabetes.

Key words: *CBG capillary blood glucose; EGA Error grid analysis; GDM Gestational diabetes mellitus; VPG venous plasma glucose; 2IC two instruments comparison.*

Introduction:

Estimation of blood glucose is influenced by various factors, including the origin of the sample (capillary or venous), sample preparation, method of analysis, and whether the estimation is done using whole blood, plasma, or serum. Although the oral glucose tolerance test (OGTT) using venous plasma glucose (VPG) is recognized as the ''gold standard'' for diagnosis of diabetes, there remain numerous logistic issues in carrying out venous plasma estimations [1]. There is a need for an accurate, easy, portable, and cost-effective method of glucose estimation to carry out large-scale screening for diabetes and there by obtain reliable prevalence estimates for diabetes. Point of care testing instruments like a glucometer is an obvious alternative to screen for diabetes. The question then arises as to how accurate and how reliable the glucometers are, and whether the capillary whole-blood glucose values obtained from the glucose meters are comparable to the VPG values.

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Some studies have reported that CBG are higher than VPG values in both the fasting as well as the 2-h post-load states. Others have reported that capillary values are higher than venous values in the fasting state but the reverse is true in the 2-h post-glucose (PG) load state. These variations in the results obtained by various studies indicate that there still exists much controversy regarding the accuracy of CBG estimation [2]. The pregnant women are not too willing to permit venous blood to be drawn for estimating plasma glucose (VPG) [1, 2]. In Europe, most blood sugar determinations are performed with capillary whole blood using portable blood glucose meters, which is a patient-friendly approach. Hence, we also wanted to ascertain the use of Glucometer to diagnose GDM in our population that offers the same precision as laboratory analysis as a diagnostic testing in GDM [3]. Thus the aim of the present study was to compare CBG measurements with VPG measurements after a standard glucose load in pregnant women of Asian Indian origin, and to determine the sensitivity and specificity of CBG in comparison with VPG in diagnosing GDM. The expected outcome of this study is to suggest a method that would be convenient, and economical to diagnose GDM in the community [4-10].

Materials & Methods:

This is a cross sectional prospective study conducted at the Biochemistry laboratory of Niloufer hospital, Hyderabad, Telangana, India. Subjects were pregnant women of various gravidae with 24-28 weeks of gestation, who underwent preliminary examination at antenatal OPD in the department of Obstetrics of & Gynecology of the same hospital and were sent to laboratory for routine investigations and or OGTT. This study was approved by Institutional Ethical Committee of Osmania Medical College, Hyderabad. Study conducted for a period of one week in the month of May 2015.A standard questionnaire and informal consent were explained in their language and data were recorded. Details of smoking and alcohol use, first degree family history of diabetes and hypertension, and demographics were recorded. Race/ethnicity was self-Test strips lot 24629831; expiry 02-2016. The VPG estimations were done within 40 minutes after obtaining plasma. The laboratory was masked to the CBG values. All testing were done by same qualified and experienced lab technicians and under ambient conditions.

Quality control: The average coefficient of variation (CV) for the laboratory internal quality control for the VPG during the study period was 2.3% for the abnormal (Erba path) glucose range (mean ± SD, 301 ± 6.9mg/dL) and 3.24 % for the normal glucose (Erba Norm) range (mean± SD, 77.0 ± 2.5mg/dL). External Quality Controlled by Christian Medical College, Vellore. The identified. We excluded those subjects who were non tolerant to glucose load (vomiting), were given a later date for OGTT screen. Pre gestational diabetes and known thyroid illness were not included in this study. Those women whose glucometer readings were either 'low' or 'error', and not willing for repeating the finger prick ,were detained from this study. Thus, we could collect data of total no. of subjects (N) 182 for a period of one week and we couldn't afford this study for large no. of subjects for a lack of resources like glucose strips. The clinical characteristics are mentioned in Table 1.

After obtaining written consent, Subjects were then explained the procedure and were asked to consume 82.5 g of oral glucose (Glucon-D, Heinz India Pvt Ltd., India) equivalent to 75 g of anhydrous glucose) dissolved in 200 mL of water, irrespective of their last meal or feed status [11,12]. The time of glucose consumption was noted. At 2 hours (120 min), venous blood sample was drawn and simultaneously a finger prick test was performed. This single-step procedure has been approved by Ministry of Health, Government of India and also recommended by W.H.O [13]. CBG values are declared immediately to the curious patients but asked them to collect VPG reports the next day (VPG results are reported on the following day) making them to understand that CBG is studied for comparison.

Sample collection: i) 2ml of Venous Blood in a grey top (Sodium Fluoride as anticoagulant) vaccutainer to obtain plasma by centrifuging immediately for VPG estimation ii) one drop of finger prick capillary blood for CBG (sample volume < 2µL); with the finger prick pen using each a new disposable lancet for all subjects.

Methodology: A) For VPG: Glucose oxidase – Peroxidase enzyme (GOD-POD) method, VPG estimated by Erba Transasia Semi Auto analyzer Chem 5+V2. B) For CBG: Glucose Dehydrogenase (GDH-PQQ) enzyme color (yellow to green to grey) reaction and Photometric detection in ~ 5 seconds, by Accu-check Active (Rosche Diagnostics) code 298 & plasma calibrated glucometer (repeatability and reproducibility i.e., within series & day to day imprecision was < 3% and linearity up to 600 mg/dL). glucose meter used in the study was routinely calibrated (after every 19th sample) using the control solutions (level1, 41-71 mg/dL; level 2, 136-184 mg/dL) provided with the instrument, and the mean CV was 2.9%. Statistical Analysis was done by MS Excel sheet, SPSS 20 version for windows (IBM® SPSS® solutions), Graphpad Prism 6 Demo version (La Jolla, CA) and EP Evaluator® 11.2.0.23 (Data innovations, LLC) for 2Instrument Comparison (2IC) & Error Grid Analysis. Continuous variables are shown as mean ± SD, and categorical variables presented as percentage. Student't' test and chi square test are used for comparing the groups wherever appropriate. The alpha

level for all analyses was set as 'P' value less than 0.05. Accuracy of glucometer checked with standards of ISO 15197:2003.Correlation coefficient (to determine the linear relationship between the methods in estimating the 2-h glucose value). Method comparison done by Linear regression (to find the predictive equation, in order to predict 2-h PG value of the venous blood sample corresponding to the observed CBG), Bland Altman plot, 2 instrument comparison and error grid analysis. Receiver operator characteristic & Area under curve analyses (to analyze the predictive power of the constructed equation Sensitivity, specificity, false positive rate and false negative rate were computed to validate the capillary method in detecting GDM) were done. The diagnosis of GDM was based on having a 75 grams 2-h post glucose value (VPG) of 140 mg/dL (7.8mmol/L) World Health Organization criteria [12, 14].

Results:

Table 1.Clinical Characteristics of Participants

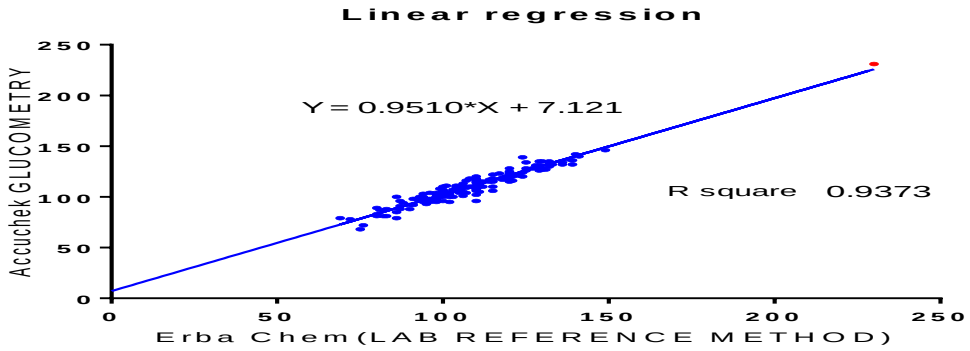
characteristic	
N (total)	182
Age (years) (mean ± SD)	25 ± 8.2
Gestational weeks (mean ± SD)	21±7.2
Positive Family history of Diabetes	22%
BMI(kg/m2) (mean ± SD)	21.5±5.57
Past H/O GDM	3
H/O loss of pregnancy	1
Primi gravida G1	(101)55%
≥G2	(81) 45%

In the present study we observed that out of 182 subjects, 4 pregnants were diagnosed to have GDM with a measured incidence 2.19%.All those 4 GDM cases possessed risk factors like obesity, glucose intolerance in previous pregnancy, family history of type 2 DM. These subjects, 55% were primi gravidas, did not show any statistical association to glucose intolerance. Increasing age also didn't correlate to development of GDM as three out of four subjects who had GDM are younger than 25 years of age. The prevalence of risk factors is shown in table 2. The venous plasma glucose (mean ± SD) was 108 ± 19mg/dL and capillary blood glucose 111 ± 17 mg/dL. The average glucose value was lower in plasma by 3mg/dL when compared to capillary whole blood. Linear Relationship between VPG and CBG was measured using Pearson correlation coefficient (measuring interval for Erba Chem 69 to 230 mg/dL and Accu Chek 68 to 231mg/dL**)** r = 0.9681 ; p <0.001 (****). In order to further establish the relationship between glucose values obtained by VPG and CBG, the linear regression model was used (CBG as an independent variable and VPG as dependable variable to calculate the VPG value from the given CBG value), and linear regression equation constructed to predict the intravenous value for a given capillary value: Equation Y = 0.9510*X + 7.121; R^2=0.9373 and 95 % confidence interval for the slope was observed between 0.9151 to 0.9869; Y intercept 3.145 to 11.10 when X=0 (Figure 1).

Table 2.Prevalence of Risk in Study Population:

Risk factors	N	Non GDM	GDM	P value
Age > 25 y	50 (27%)	49	1	0.021
BMI > 25	30(16.5%)	27	3	<0.001*
Positive family H/O DM	62 (34%)	58	4	<0.001*
Past H/O GDM	2(1%)	-	2	<0.001*
H/O loss of pregnancy	10(5.5%)	10	-	0.25
Primi gravida G1	101 (55%)	99	2	0.056
G2	81 (45%)	79	2	0.045

Figure 1: Regression of CBG versus VPG (outlier shown as red)



The predicted capillary 2-h PG value and the observed intravenous value in diagnosing the GDM are given in Table 3.

Table 3.Observed Vpg 2-H Value & Predicted 2-H Value By Cbg

Cbg 2 Hr Value	Vpg 2 Hrs Values				
	> 140 Mg/Dl		< 140 Mg/Dl		
	N	%	N	%	Total
> 140 Mg/Dl	4	100 (Sensitivity)	2	1.2	6
<140 Mg/Dl	0	0	176	98.8 (Specificity)	176
Total	4	100	178	100	**182**

Receiver operator characteristic analysis was done for the predicted values using the fitted equation, it was observed that area under the curve (AUC) was 0.994 (Figure 2).Capillary method had a sensitivity of 100 % and a specificity of 98.8 % at 140 mg/dl. False negative rate was 0 % and false positive rate was 1.2%. Accuracy of capillary glucoses was assessed using the International Organization for Standardization (ISO) 15197: 2003 standard, which states that 95% of the individual results for the glucose meter shall fall within ± 15 mg/dL of the results at glucose concentrations ≤ 75 mg/dL and ± 20% at glucose concentrations ≥ 75mg/dL [15].The performance of our glucometer is satisfactory as per the criteria mentioned is shown in Table 4. The constant bias (CB) was calculated as 1.7% and the SD value 4.3 with 95% limits of agreement (LoA) - 6.7(negative bias) to +10 (positive bias) and (is the measure of imprecision, IP) is shown at Figure 3, the Bland–Altman plot; Two Instruments Comparison (2IC) ; the difference between the two methods was within allowable error (within Allowable Total Error of Target value ± 6 mg/dL or ±10%, whichever is greater) for 176 of 182 specimens (96.7%). The average Error Index (Y-X)/TEa was - 0.16, with a range of -1.40 to 1.46. The largest Error Index occurred at a concentration of 96 mg/dL. The test considered as 'Passed'.

Figure 2: The Receiver Operator Curves Showing The Performance Of Cbg Using The Vpg As The Reference Method To Predict Gdm With A Cut Off Value Set To 140mg/Dl.

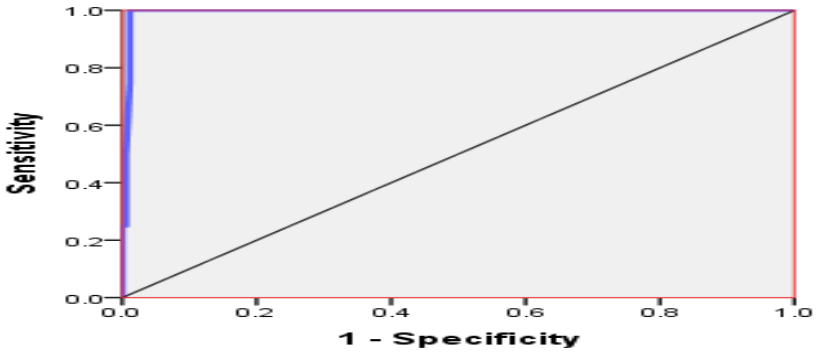


Table 4 : Accuracy of the Glucometer Comparing Against Lab Analyzer Using ISO 15197:2003 Criteria

Glucose values (mg/dL)	Accuracy of glucometer Accu Chek / Erba 5+V2 analyzer
< 75 (30%)	n=55
Within ± 15	53/55(96%)
≥ 75 (70%)	n=127
Within ± 20%	126/127 (99%)

Fig 3. Bland–Altman plot showing the percentage total error between capillary glucose (CBG) (by Accu-Chek glucometer) and venous plasma glucose (VPG) (by Erba Chem5+ V2) at 95% limits of agreement. The narrow black line close to the X axis is the bias. The two outer parallel dashed lines are the 95% limits of agreement -6.7 to 10.

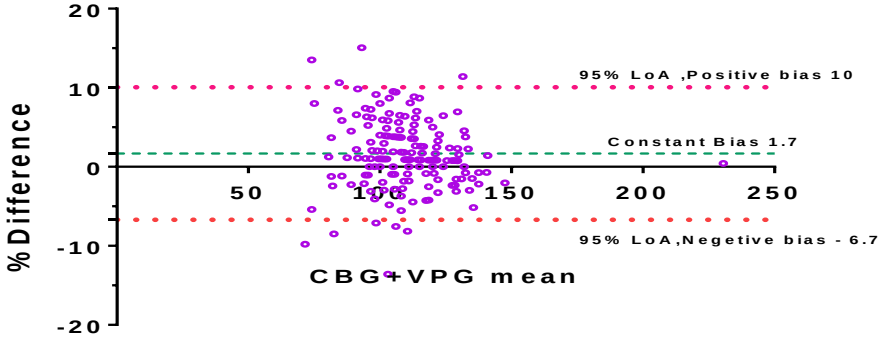


Figure 4a.Scatter plot shows the data points, together with the 1:1(Y=X) line with TEa boundaries. The plot does not show the regression line. Figure 4b.Error Index plot shows error index. Points that fall in the shaded area have an unacceptable EI (>1.00 or < -1.00).

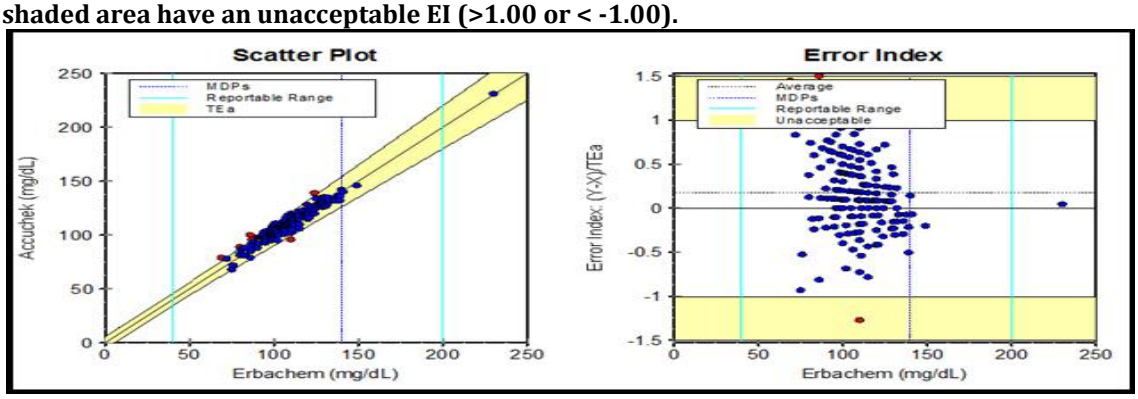
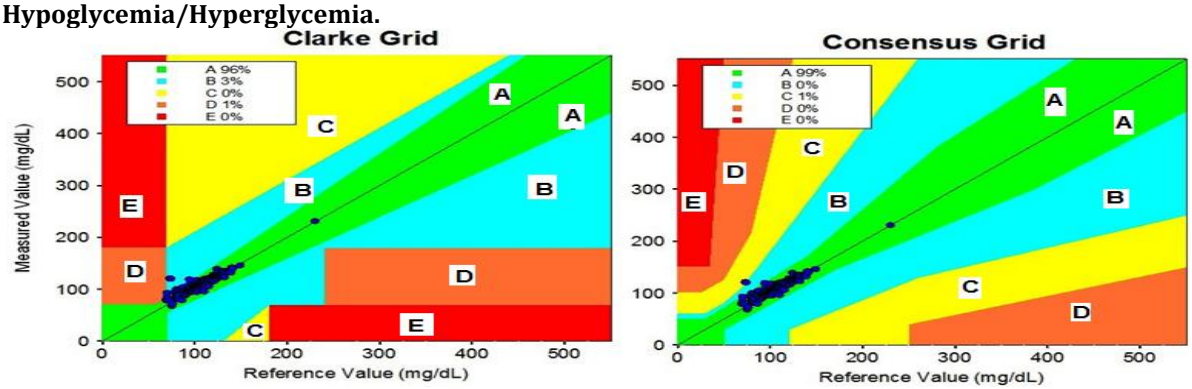


Fig.5a &b: Error Grid Analysis of glucometer, Zone-A: Clinically accurate, within +/- 20% of laboratory reference (a; 180/96% b; 174/99%), Zone-B: Error greater than +/- 20%9, Zone-C: Unnecessary corrective treatment, Zone-D: Failure to detect the Hypoglycemia/Hyperglycemia & Zone-E: Erroneous treatment of Hypoglycemia/Hyperglycemia.



Clarke and consensus Error Grid results for all the glucometers (Figure 5A & 5B respectively). X-axis represents the laboratory reference values and Y-axis represents the glucometer values. The error grid is divided into five zones. Ideally all the values should be inside the A-Zone but if some percentage is inside the B Zone then it may be considered as clinically accepted.

Discussion:

GDM is diagnosed in the second or third trimester of pregnancy that is not clearly overt diabetes [16]. GDM is a powerful predictor of future development of diabetes within 10 years after the child birth which is a modifiable risk factor by life style changes or exercise [17]. Universal screening in place of selected screening is preferred to curb the maternal morbidity, perinatal mortality and alerting the mother as well as child for future risk of developing DM. Some GDM cases may represent preexisting, but undiagnosed, type 2 diabetes. Therefore, women with GDM should be screened for diabetes 6–12 weeks postpartum according to the OGTT criteria for non pregnant women and lifelong screening for diabetes should be performed at least every 3 years according to standard criteria for non pregnant women [18, 19]. In the Indian scenario, 11 folds increased risk observed, for glucose intolerance when compared to Caucasian women [20].

ADA recommends 'two step procedure' with 50 g glucose challenge test (GCT) and one hour glucose value > 140 mg/dL, warrants further the second step on a different day with 100g oral glucose load (OGTT) for confirmation of GDM by *Carpenter and Couston criteria* which requires 4 samples i.e., at 0, 1, 2, 3 hrs [21]. But according to Dornhost A et al, 23% of pregnant women who were GCT positive in the first visit, failed to return for the definitive OGTT [19].The adverse maternal and fetal short term and long term morbidity occurs in the inflection point of maternal 2 h plasma glucose >140mg/dL, the mean glucose level at which odds for adverse outcomes reached 1.75 times the estimated odds of these outcomes, imparts clinical significance to the figure '140mg/dL'. This 'one step-approach', standardized by WHO, for the diagnosis of GDM using a 75g OGTT with a threshold plasma glucose concentration of > 140mg/dL at 2 hours, similar to that of impaired glucose tolerance, IGT (>140 & 199mg/dL) outside pregnancy [13]. The one-step strategy was anticipated to significantly increase the incidence of GDM (from 5–6% to; 15– 20%), primarily because only one abnormal value, not two, became sufficient to make the diagnosis [13, 15].

The glucose concentrations are little affected by the time since the last meal in a normal glucose tolerance woman, whereas it will, in a woman with diabetes, by the cascading exaggeration of glycemic excursions [12]. Considering this as key point; the fasting status is disregarded as a pre requirement to undergo OGTT. The DIPSI guidelines recommend screening on the first antenatal visit with 75g OGTT disregarding the feed status. Thus a new, simple, and feasible definitive method to diagnose GDM got evolved which can be done as a random investigation by taking only a single blood sample, which is a less painful and more acceptable one, without affecting the routine of the pregnant women, motivating them to undergo such an important test.

But as, glucose is a very unstable parameter and degrades soon by glycolysis in blood cells, the transport of blood samples at the required temperature within a short period of time to a central laboratory for processing , is costly and not feasible and non compliant. The vast population of India (1.2 billion), shortage of phlebotomists, no availability of quality controlled laboratories, and varied methods of glucose estimation are some of the major challenges in using VPG estimation for diagnostic studies [1].

A simple finger stick test, which uses less than one drop of blood (1-2 µL only) and gives the glucose reading in a few seconds, is much more acceptable [22]. Several studies [23-26] have elicited the accuracy and increasing usefulness of glucose meters as screening tools though other studies have yielded controversial results [27]. Dacus et al.found by a simpler linear regression that the cutoff value for 2-h PG of ≥ 7.89mmol/L(140mg/dL) had a strong correlation between capillary Accu Chek and the laboratory values, and one value may be substituted for the other [28]. However products containing maltose, icodextrin (which is converted to maltose), or Galactose spuriously increase results obtained with point of care glucose meters that use glucose dehydrogenase pyrrolo-quinoline quinine (GDH-PQQ) [29].

The present study was carried out to compare capillary whole-blood glucose versus plasma glucose estimation to validate the use of capillary whole-blood glucose estimation by a glucometer as a screening tool for GDM. Weiss PA et al. study revealed that CBG values best approximated VPG values in healthy populations. It is interesting that, in the diagnosis of GDM, the glucose measurement by CBG and VPG did not differ in the 1-h level (177 vs. 171 mg/dL) or the 2-h level (141 vs. 137mg/dL) [30]. Irjala et al examined the interrelations of CBG and VPG with respect to gestation, glucose tolerance, and analytical method. No significant capillary–venous difference was seen when VPG was estimated by the glucose dehydrogenase method [7, 31, 32, and 33]. Colagiuri S and Foss-Freitas MC et al. found a difference of 5-9mg/dL of VPG from CBG at 2h post glucose load may not discourage the use of glucometer as more studies are coming up in favor of CBG [26, 34].

The Accu-chek glucometer which we used in this study was handled by a single user to keep the variability to minimum. The performance of our glucometer with respect to ISO 15197: 2003 performance criteria for values of > 75 mg/dL (70% of results; as we were testing the 2h OGTT) were within ± 20% and combining the data obtained for ±15 mg/dL and ±20% yields the values required for assessment of the ISO 15197:2003 requirements showed 99% accuracy, with a coefficient of variation (CV) 3% (< 5).

Correlation of glucometer and laboratory values of glucose was high, with a coefficient of correlation value r = 0.9681, but this is only a linear relationship and informs about the random error, not agreement between these two methods as correlation is dependent on range of the data and also precision of the measurements [35,36]. Hence, we have done method comparison analysis by the popular statistical methods in order to establish glucometry as an interchangeable method for the analyzer. By using linear regression model, the equation was constructed to predict laboratory glucose value for a given glucometer CBG result, Y = 0.9510*X + 7.121 (for example, if glucometer reads 100 mg/dL, then the predicted lab value would be 98 mg/dL).The R^2 value was 0.9373 and 95 % confidence intervals (CI) for the slope and the Y intercept were 0.9151 to 0.9869 and 3.145 to 11.10 (when X=0) respectively; this interval was narrow, indicating precision of the regression coefficient (Figure 1).These values of best fit regression line indicates a significant (P < 0.0001) deviation from the line of equality (slope=1; intercept=0), but this systematic error (SE) or calibration bias were within the total allowable error < 10% as defined for the glucose estimations by CLIA[37,38].

Bland - Altman (difference) Plot is a plot of the differences against average results of the methods and gives information on the relation between the differences and concentration which is useful in the context of how to adjust for an irregularity e.g., by changing the method to correct for the non linearity and or restricting the analytical measurement range[29]. This study revealed a constant bias 1.7% with SD 4.3 (95% CI: -6.7 to 10) which is the random error in acceptable limits inferred as the good agreement between these two methods. The plot has more linear and homogeneous dispersion of values around the concentrations of glucose 75mg/dL to 150mg/dL (only a single outlier 231mg/dL; Q=1%), because we measured post glucose load values and there is no data for the entire physiological range for glucose.

Alternate Method Comparison (AMC) provides a flexible approach to Method Comparison. It is designed to be used for most routine method comparison analyses. Two instruments comparison (2IC) is a simple and straight forward method to compare the two methods without using linear regression [39,40]. 2IC is considered to be superior than regression based comparisons which measure statistical equivalence based on bias inspite of random errors (RE) larger than TE a; but 2IC considers bias between the methods bound by TEa, though the errors are non-random {i.e., (CB) constant & (PE) proportional bias = (SE) Systematic Error}. Error index is the ratio of (Yi - Xi) / Allowable Error (evaluated at X.) The error index is calculated for each X-Y pair. An index greater than 1.00 or less than -1.00 is unacceptable—it means the difference between the methods exceeds Total allowable error (TE a).Our study proved that these two methods are same (i.e., are clinically identical), as the difference between the methods does not exceed the TE a (predefined by CLIA) thus the glucometry (test method) is said to be 'passed'.

Error Grid Analysis (EGA) is a very specific form and a condensed approach of method comparison that compares two glucose methods using Clarke and Consensus diagrams [41,42]. It is a scatter plot area is divided in to five zones, A-E, which reflect the medical risk of error. The new EG was created to reflect the opinion of a large number of clinical diabetes experts. The consensus EG lacks the discontinuities of Clarke et al.'s EG but, otherwise, it gives similar results. Overall, the new EG was more tolerant of SMBG errors.

Error-grid analysis demonstrated that 96% of the results fell in zone A and 3% B for Clarkes and 99% in A zone for consensus grid which is same. Our findings are similar with those of Brunner et al found over 99.7% of the results to be in zone A and B [43]. These results suggest that glucometer is reliable for measuring capillary glucose levels. On the other hand, we found 1% of the results in zone C and 1% in Zone D (Clarkes & consensus grids respectively) may have no effect on patient outcomes. Therefore glucometer as compared with the lab reference method can be safely used in diagnosis of GDM.

After demonstrating the clinical equivalence of the methods, we did Receiver Operator Curve analysis (ROC) to prove the glucometer as a method with high sensitivity which is a prerequisite of any good screening test [44]. The area under the curve represents the probability that the assay result for a randomly chosen positive case will exceed the result for a randomly chosen negative case. ROC analysis was done for the predicted values using the fitted equation (Fig. 2) indicate that the area under the curve (the area measures discrimination, the ability of the test to correctly classify those with and without the disease) is 0.994. This implies that the prediction power of the constructed equation is very high at 140 mg/dL (as the

cut off value), all four GDM cases were detected by the glucometer giving 100% sensitivity to CBG method and two subjects were false positive with comparison to laboratory estimation of glucose, thus 98.8% specificity was achieved. The false-positive rate (FPR) is as low as 1.2 %, and the false negative rate (FNR) is zero.

There are some limitations to our study caused by the limited knowledge about patient hematocrit, oxygen saturation, hydration and viscosity status, and the existing interfering substances that are affecting the measurement of these glucometers.

Conclusion:

The NIH panel reported the lack of clinical trial interventions demonstrating the benefits of the 'one-step strategy' and the potential negative consequences of identifying a large new group of women with GDM, including medicalization of pregnancy with increased interventions and costs. But ADA recommends diagnostic criteria changes in the context of worrisome worldwide increases in obesity and diabetes rates with the intent of optimizing gestational outcomes for women and their offspring. Hence whether VPG or CBG is used for the diagnosis and monitoring of GDM, clinical judgment is must in making the final decision. And it is safe to diagnose diabetes using a glucometer i.e., CBG, provided one uses the equipment with high precision and given that continuous quality assurance procedures are used.

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