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Original Research Article

Performance Comparison of Point-of-Care Testing (Glucometer) and Laboratory Reference Glucose Oxidase Peroxidase (GOD-POD) Method for Glucose Measurement in Neonatal Jaundice

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Abstract

Objective: This retrograde study was designed to compare between POCT glucometer and Laboratory reference method for glucose measurement in neonates especially in Neonatal Jaundice. The main objective of the study was to find the acceptability of POCT Glucometer against laboratory reference method. ***Material and Methods***: 200 samples data were collected from the laboratory of neonatal jaundice. The samples neonatal jaundice with total Bilirubin >2mg/dL was considered for analysis., Glucose dehydrogenase method(Glucometer) and GOD-POD method (Reference Laboratory method) was used to measure glucose measurement in samples that were obtained. ***Results:*** Glucometer accuracy was evaluated using linear regression, Passing-Bablock regression, Bland-Altman analysis. There was no significant difference. Clarke Error Grid analysis, >98% results were in zone A. The Mean bias of Glucometer was 1.9%; with P <0.05**.** ***Conclusion:*** POCT Glucometer (Glucose dehydrogenase method) measurement performance was acceptable in hypoglycemic range especially in Neonatal Jaundice.

Keywords: Neonatal Jaundice, Hypoglycemia, POCT, Glucometer, GOD-POD, Glucose Dehydrogenase.

INTRODUCTION

Different methods and instruments for rapidly measuring blood glucose concentrations have entered the healthcare sector in the last 10yrs [1]. Rapid and accurate monitoring of blood glucose levels in a neonatal intensive care setting is important in managing glycemic control. Blood glucose meters developed is commonly used for glucose measurements in NICU. They have become more important in monitoring glycemic control, especially in Neonatal Jaundice [2]. The sample for glucometer is whole blood, collected from capillary vessels; however serum obtained by clotting is used for lab analysis [3]. It is a known fact that, variations exist with glucose estimation of whole blood and serum [4]. Establishing the accuracy of glucometers, however, is challenging and more difficult in Jaundice of neonates. Validation of these devices is usually carried out by comparing the measurement of glucose concentrations with an accepted laboratory method; evaluating precision and accuracy against standard methodology [5]. However when glucometers are tested, the valves of glucose is not evaluated adequately, since very few samples are obtained in low glucose concentrations. Burrin J. M *et al.*, [5] tested that co-relation did not exist between devices at low glucose concentrations .The objective of the study was to evaluate the glucose levels of neonates, especially in Neonatal Hypoglycemia of NICU, measured with Glucometer and to determine their precision and the bias relative to serum concentrations measured in laboratories with reference glucose oxidase peroxidase (GOD-POD) method [6].

MATERIALS AND METHODS

Data was retrieved from lab records for Blood samples referred to Clinical Biochemistry Lab, from admitted neonates in NICU for Bilirubin measurement. Glucose done on Glucometer was collected from NICU medical records. A total of more than 200 case records were analyzed.

Inclusion Criteria

- Newborns < 4weeks
- Total Bilirubin levels >2mg/dL

Exclusion Criteria

- Newborn >4weeks
- Total Bilirubin > 25mg/dL
- Blood Glucose levels > 600mg/dL
- Septicemia cases

- Lipid Disorder cases

Samples

Collection of Sample at Site

Whole capillary blood was collected by Heel puncture method and glucose measurement were done immediately on Glucometer and recorded. Remaining whole blood was collected in a BD Microtainer® tube with NaF/Na2-EDTA additive and sent to lab, samples were centrifuged at 3500g for 10 minutes and blood glucose was assayed in plasma on MISPA NANO fully automated chemistry Analyzer (reference laboratory instrument). Glucose assayed with reagents employing reference method with Glucose oxidase peroxidase method was used. The method is calibrated and validated with controls Erba Norm and Erba Path. Inter-assay precision studies were performed as recommended by National clinical chemistry laboratory standards (NCCLS) [7].

Glucometer

Glucometer (POCT) employs method with glucose-dehydrogenase method. Detection limit range 10mg/dL to 600mg/dl. Instrument is calibrated with supplied controls with instrument [8].

Statistical Analysis

Glucose levels obtained from POCT Glucometer and reference method were compared for descriptive statistics on SPSS Software. $P<0.05$ was considered statistically significant. Each distribution was examined for normality by Kolmogorov-Smirnov test. The difference between laboratory method and Glucometer method concentrations was tested by paired t-test. Glucometer accuracy will be evaluated using four methods and respective commonly used criteria: linear regression, Passing-Bablock regression, Bland-Altman analysis, Error Grid Clarke analysis.

RESULTS

All the above mentioned methods were used to analyse the obtained data using SPSS software.

Table-1: Paired samples t-test

	Glucometer (Glucose dehydrogenase)	Laboratory Reference method (GOD-POD)
Sample size	200	200
Arithmetic mean	59.56	58.86
95% CI for the mean	51.25 to 63.64	54.92 to 65.16
Variance	94.51	64.523
Standard deviation	10.23	7.93
Standard error of the mean	1.2365	0.6583

Table-2: Paired samples t-test

Mean difference	-3.561
Standard deviation of mean difference	5.6523
Standard error of mean difference	0.6214
95% CI	-2.9645to -0.9641
Test statistic t	-4.08956
Degrees of Freedom (DF)	89
Two-tailed probability	P = 0.0026

Bias (Table-1)

Bias was assessed by calculating the mean difference (%) between the Glucometer device results and results measured with reference method. Measurements did not differ significantly (P = 0.0026)

Linear regression (Figure-1)

Coefficient of determination R^2 =0.7561, with acceptable linearity for Accu-chek $P<0.0001$.

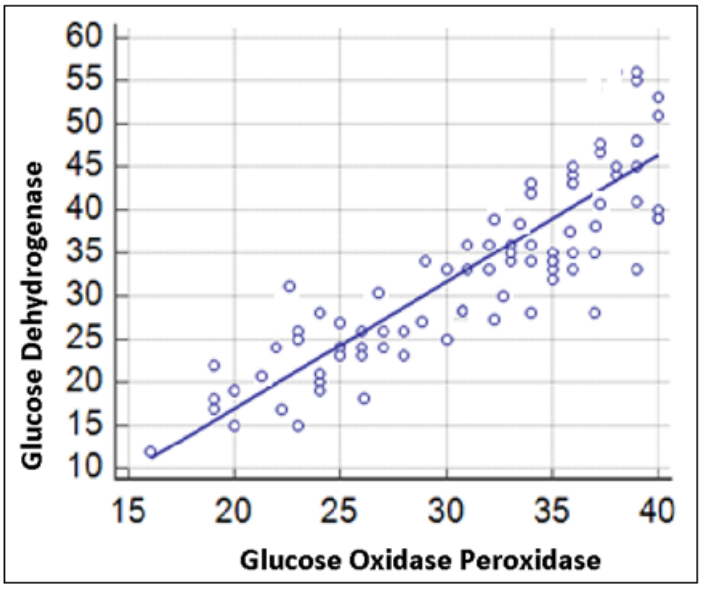

Fig-1:

Passing-Bablock regression (Figure-2)

The regression equation was: y = -20.14 + 1.7 x and there was no significant deviation from linearity. (P=0.03)

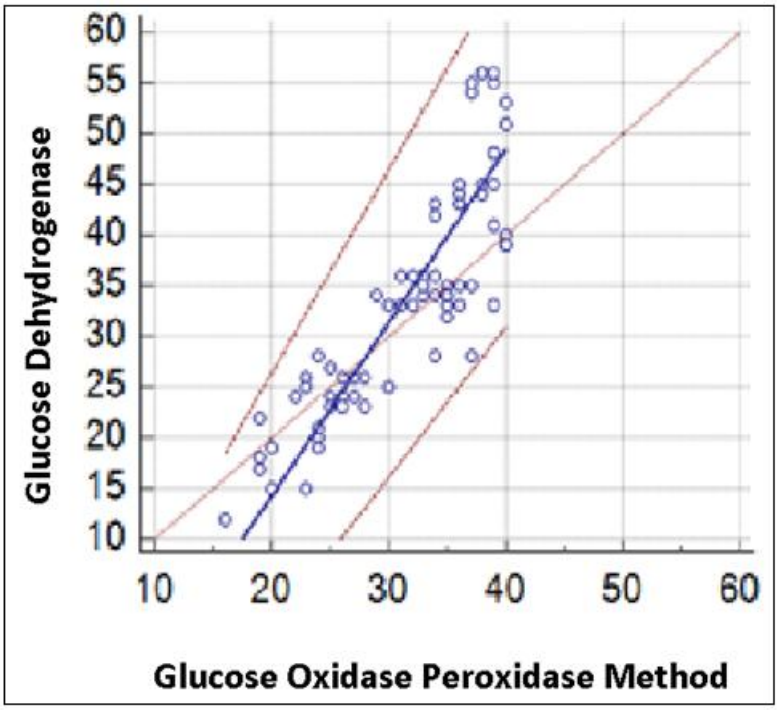

Fig-2:

Bland-Altman analysis (Figure-3)

Horizontal lines were drawn at the mean difference, and the mean difference ± 1.96 times the standard deviation of the differences [9]. The mean difference of the two glucose measurements was 2.37 mg/dL.

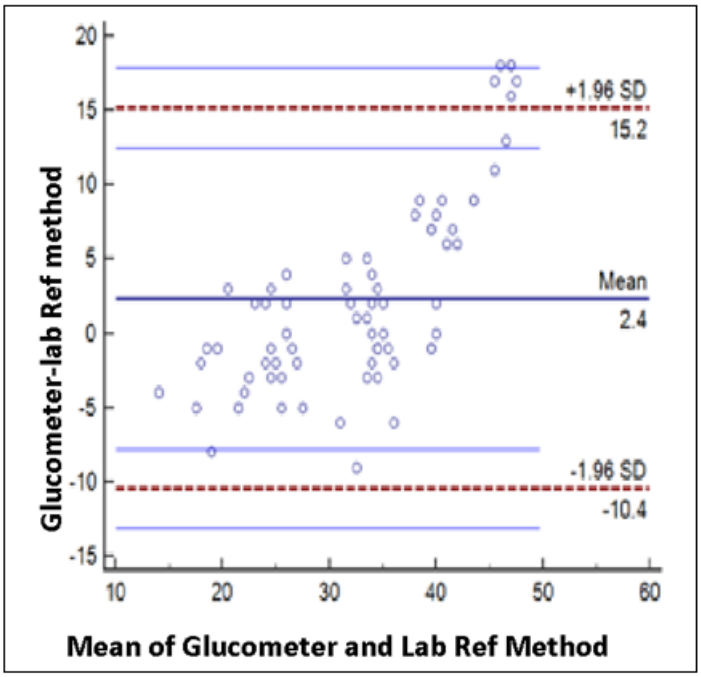

Fig-3:

Error Grid analysis (Figure-4)

Values in zone A and B are considered to be clinically accurate. Values in zone A do not vary by more than 20% from the laboratory reference value. >95% values were found in Zone A.

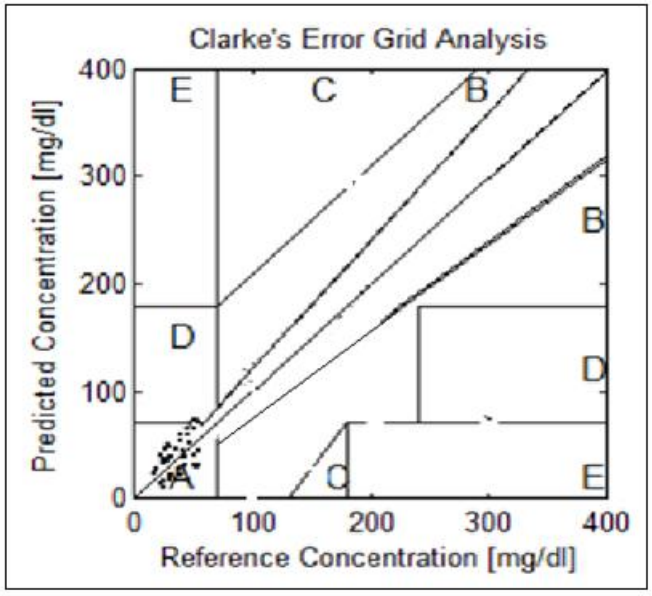

Fig-4:

DISCUSSION

The analytical performance of POCT does not match with that of lab reference method, its turnaround (TAT) and amount of sample required adds an advantage to immediately make a decisions in emergency conditions especially in casualty and NICU's [2]. Neonatal Jaundice, measurement of blood glucose levels in the newborn is important in order to prevent and treat hypoglycemia effectively, therefore reducing the risk of adverse neurological outcomes. Time delay in obtaining accurate result from reference lab method further delays treatment to be started. Instead of placing the patient at potential risk, treatment should be started at the earliest. POCT blood monitoring is key, which provides bridge between the neonates at risk for hypoglycemia and time to get accurate results from the reference lab. Our study was similar to studies done earlier for glucose concentrations by POCT glucometer and laboratory method, which did not find significant difference [10].

Considering most of the values in hypoglycemic range and >98 % values falling in zone A of error grid analysis, which holds good to make a clinical decision [10]. There is small difference in the glucose concentrations of capillary and venous samples which can be neglected to make immediate clinical decision for treatment of hypoglycemia instead awaiting lab results [11, 12]. The study results of POCT Glucometer compared with reference hexokinase method are acceptable.

CONCLUSION

The comparison of POCT Glucometer gives acceptable results when compared GOD-POD lab reference method, which can be very helpful in monitoring glucose concentrations in critically ill patients and neonates of hypoglycemic conditions especially in neonatal jaundice. POCT Glucometers saves decision time for clinician's time to start immediate treatment, instead waiting for highly accurate results from Lab.

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