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RESEARCH ARTICLE

A COMPARATIVE STUDY OF POINT-OF-CARE TESTING ACCU-CHEK AVIVA AND LABORATORY REFERENCE HEXOKINASE METHOD FOR GLUCOSE MEASUREMENT IN NEONATES

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ABSTRACT

Objective: This study was designed to compare between POCT glucometer and Laboratory reference method for glucose measurement in neonates especially in hypoglycemic conditions. It also evaluated the acceptability of POCT glucometer to measure blood glucose concentration in neonatal hypoglycemia.

Material and Methods: 163 samples were collected, only 70 samples were included in this study. The cut off for glucose concentration <40mg/dL was taken for neonatal hypoglycemia since there is no specific demarcation exists in hypoglycemia of neonates., Glucose dehydrogenase (Accu-Chek Aviva) and Hexokinase 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 Accu Chek Aviva was 2.3%; with P <0.003

Conclusion: POCT Accu-chek Aviva glucose measurement performance was acceptable in hypoglycemic range.

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INTRODUCTION

Different methods and instruments for rapidly measuring blood glucose concentrations have entered the healthcare sector in the last 10yrs (American Diabetes Association). 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, both in hypoglycemia and hyperglycemic states (Lockyer *et al*., 2014). The sample for glucometer is whole blood, collected from capillary vessels; however serum obtained by clotting is used for lab analysis (Youh, 2001). It is a known fact that, variations exist with glucose estimation of whole blood and serum (Karon *et al*., 2007). Establishing the accuracy of glucometers, however, is challenging and more difficult in hypoglycemia of neonates.

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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 (Burrin *et al*., 1986). However when glucometers are tested, the low valves of glucose is not evaluated adequately, since very few samples are obtained in low glucose concentrations. Burrin JM *et al* 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 hypoglycemic states of NICU, measured with Accu-chek glucometers and to determine their precision and the bias relative to serum concentrations measured in laboratories with reference hexokinase method.

MATERIALS AND METHODS

Subjects

After obtaining, consent from parents and clearance form ethical committee. Blood sample was collected from admitted neonates in NICU for a period 11 months. 163 samples were

collected and only 70 were included to study glucose levels in neonatal hypoglycemia. However, since, there is no fixed low glucose level for neonatal hypoglycemia, due to controversies regarding definitions (Marvin *et al*., 2000). Hence in this study cutoff glucose level of 40mg/dL was considered. Glucose concentration >40mg/dL by lab reference method was excluded from study.

Samples

Blood collection was done by a skilled phlebotomist under strict aseptic precautions. Whole capillary blood was collected by Heel puncture method and glucose measurement was done immediately on glucometer, from the first drop of blood. 500 µL of whole blood was then collected from each patient in a BD Microtainer® tube with NaF/Na2-EDTA additive, centrifuged at 3500g for 10 minutes and blood glucose was assayed in plasma on DADE BEHRING Dimension Xpand reference laboratory instrument.

Chemistry analyzer DADE BEHRING Dimension Xpand

Glucose was assayed with original reagents employing reference method with hexokinase on DADE BEHRING Dimension Xpand . The method is calibrated daily and Bio-Rad control sera Level 1 and level 2 are run on every eight hours or/and after 100 glucose tests. Inter-assay precision studies were performed as recommended by National clinical chemistry laboratory standards (NCCLS) (Tholen *et al*., 2008). The hematocrit levels were also measured and considered.

Accu Chek Aviva Glucometer

Accu Chek Aviva Glucometer (Roche Diagnostics, Germany) employs method with glucose-dehydrogenase method. Detection limit range 10mg/dL to 600mg/dl. Instrument is calibrated with supplied controls with instrument (http://www.accessdata.fda.gov/cdrh_docs/reviews/K101299.pdf).

Statistical analysis

Glucose levels obtained from POCT Accu-chek Aviva and reference method were compared for descriptive statistics on SPSS 14.0. P<0.05 was considered statistically significant. Each distribution was examined for normality by Kolmogorov-Smirnov test.

The difference between laboratory hexokinase method and Accu Chek glucose concentrations was tested by paired t-test. Glucometer accuracy was evaluated using four methods and respective commonly used criteria: linear regression, Passing-Bablock regression, Bland-Altman analysis, Error Grid Clarke analysis.

RESULTS

Kolmogorov-Smirnov test (Figure 1): The maximum difference between the cumulative distributions, D, is: 0.2429 with a corresponding P of: 0.026

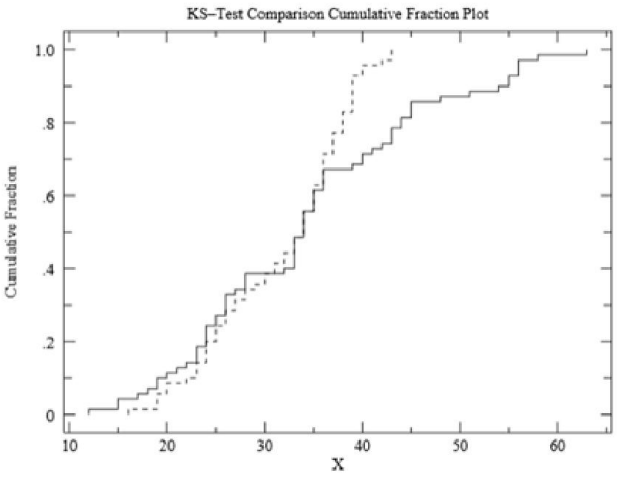

Fig. 1. Kolmogorov-Smirnov test

Paired samples t-test (Table 1)

	Accu_Check_Aviva	Hexokinase_method
Sample size	70	70
Arithmetic mean	33.9571	31.5857
95% CI for the mean	31.25 to 36.65	29.99 to 33.17
Variance	128.3894	44.4201
Standard deviation	11.3309	6.6648
Standard error of the mean	1.3543	0.7966

Paired samples t-test (Table 2)

Mean difference	-2.3714
Standard deviation of mean difference	6.5368
Standard error of mean difference	0.7813
95% CI	-3.9301 to -0.8128
Test statistic t	-3.035
Degrees of Freedom (DF)	69
Two-tailed probability	P = 0.0034

Bias (Table 2)

Bias was assessed by calculating the mean difference (%) between the Accu Check device results and results measured with reference method. Measurements did not differ significantly (bias -2.3%, P = 0.0034) between Accu Chek and reference method (mean and standard deviation were 33.95 ± 11.33 and 31.58 ± 6.66 mg/dL respectively).

Linear regression (Figure 2): Coefficient of determination R^2 =0.8048, with acceptable linearity for Accu-chek. P<0.0001

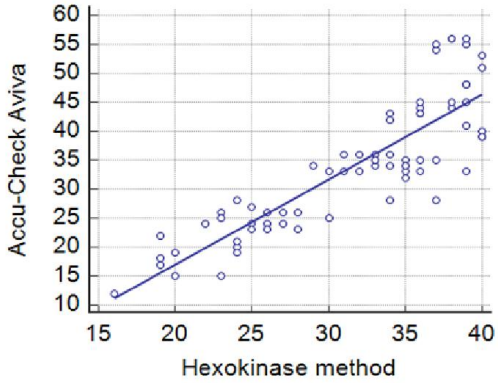

Fig. 2. Linear regression Analysis

Passing-Bablock regression (Figure 3): The regression equation was: y = -20.14 + 1.7 x and there was no significant deviation from linearity. (P=0.03)

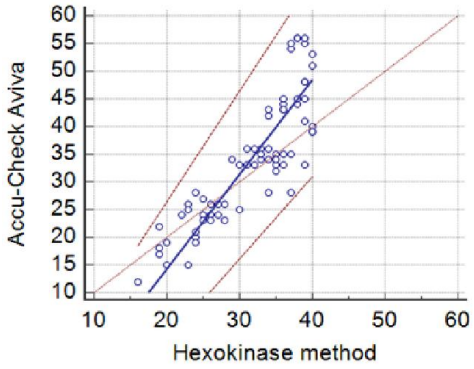

Fig.3. Passing-Bablock regression

Bland-Altman analysis (Figure 4)

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.

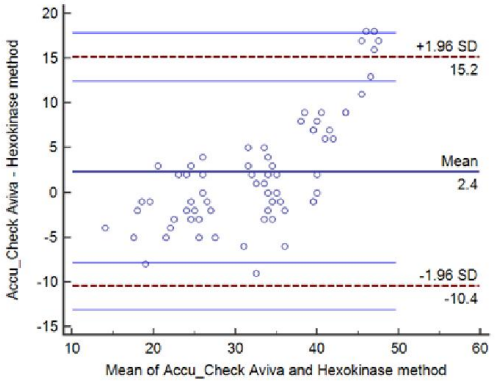

Fig. 4. Bland-Altman analysis

Error Grid analysis (Figure 5): Values in zone A and B are considered to be clinically accurate. Values in zone A do not vary by more that 20% from the laboratory reference value. >95% values were found in Zone A

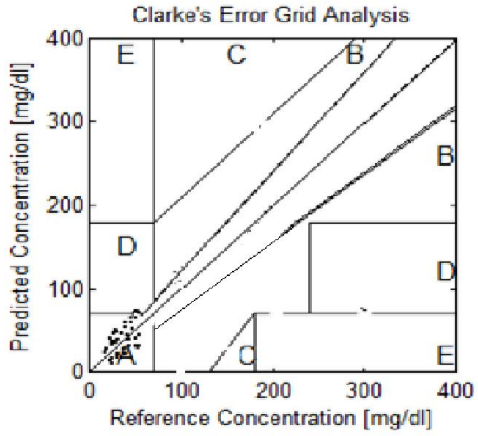

Fig. 5. Clarke Error Grid analysis

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 hypoglycemia, 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 (Tsao *et al*., 2013).

However, glucose concentrations did not co-relate significantly in the range of 15-20mg/dL and 35-40mg/dL range (figure 1). 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 (Tsao *et al*., 2013). 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 (Kanji *et al*., 2005; Boyd *et al*., 2005). The study results of POCT Accu-Check aviva compared with reference hexokinase method are acceptable. Some limitation of the study being less knowledge of patient O2 saturation, hydration and other existing interfering factors which is difficult to measure with amount of sample that can be drawn in neonates and low sample size which was due to cut off value of <40mg/dL

Conclusion

The comparison of POCT glucometer Accu-Chek aviva gives acceptable results when compared hexokinase lab reference method, which can be very helpful in monitoring glucose concentrations in critically ill patients and neonates of hypoglycemic conditions. 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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