

Comparative study of glucometer and laboratory glucose oxidase method for the estimation of blood glucose levels in neonates

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Abstract

Introduction: Hypoglycemia is one of the most common metabolic problems encountered in neonates. The glucose oxidase method used in the laboratory for determining the blood glucose concentration is precise and specific for glucose. The glucometers are often used for blood glucose estimation in NICU. **Objectives:** This is a prospective study done to determine the efficacy of glucometer in estimation of blood glucose levels in neonates in comparison with the laboratory values. **Methods:** 170 neonates admitted in NICU in Jay Kay Lon Hospital, Kota associated with Government Medical College Kota with varied symptomatology were enrolled in this study. Blood glucose estimation was done by glucometer and laboratory method using the same venous sample at the time of admission. Statistical analysis was done by using Pearson correlation. Hypoglycemia was defined as blood glucose level <45mg%. Laboratory value was taken as gold standard. **Results:** Hypoglycemia was common in neonates with risk factors like prematurity, meconium aspiration, septicemia, birth asphyxia etc. In our study Glucometer had a specificity of 98.20%, sensitivity of 64.48%, positive predictive value of 95%, negative predictive value of 83.84% and accuracy of 86.47%. There was good correlation and no significant difference between two methods in the range between 45 mg/dl and 145 mg/dl but not at very high or very low glucose concentrations **Conclusion:** The 'Point of care "device - glucometer as a sole measuring device to screen neonatal hypoglycemia is not satisfactory and confirmation with the laboratory measurements of plasma glucose is still of up most importance.

Keywords: Hypoglycemia, Neonates, Glucometer, Glucose oxidase method

Introduction

Alteration in blood glucose levels in newborns is difficult to detect clinically. Hence a reliable "point of care" device (glucometer) for early detection and treatment is needed. Hypoglycemia is one of the most common metabolic problems encountered in the newborns. The overall incidence of hypoglycemia in neonates varies from 0.2 to 11.4% [1,2]. However in the presence of certain risk factors i.e. small for date, large for date, infants of diabetic mothers, prematurity etc., the probability of hypoglycemia increases many folds [1].

Hypoglycemia in neonates can be symptomatic and asymptomatic [3,4,5]. The most common symptoms such as jitteriness, convulsions, apathy, hypotonia,

coma, refusal to feed, cyanosis, high pitched cry, hypothermia are very nonspecific and especially in small sick infants, these symptoms may be easily missed. Therefore, hypoglycemia must always be confirmed biochemically and by response to treatment. Hypoglycemia is known to be associated with brain dysfunction and neuromotor developmental retardation in both symptomatic and asymptomatic cases [1,6].

In symptomatic infant, plasma glucose concentration should be measured and if the value is <45mg%, clinical interventions aimed at increasing blood glucose concentrations are indicated [7].

The methods for determining blood/plasma glucose concentration include reductionimetric method, glucose oxidase method and hexokinase method [1,8]. The glucose oxidase method used in the laboratory for

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determining the blood glucose concentration is precise and specific for glucose [1]. As it is usually performed in the main laboratory, the results are not available quickly enough for timely appropriate management. The glucometers are often used for blood glucose estimation in NICU.

Many studies have shown that their results co-relate well with the laboratory measured glucose levels in the normoglycemic and hyperglycemic range but are not satisfactory in the lower range [9-16]. We did a comparative study of blood glucose level in neonate using glucometer and laboratory glucose oxidase method to determine the efficacy of glucometer in comparison with the laboratory values.

Materials and Methods

Source of data: The neonates admitted to NICU over a period of 3 months in Jay Kay Lon Hospital, Kota associated with Government Medical College Kota.

Study design: Prospective study

Sample size: 170

Inclusion criteria

1. Neonates admitted in Jay Kay Lon Hospital Neonatal Intensive Care Unit (NICU) associated with Government medical college, Kota.
2. Both sex

Exclusion criteria

1. Infant >28 Days
2. Neonates with PCV less than 40% more than 65%
3. Out born or referral case

Results

170 neonates admitted in NICU of JKLON hospital, Kota were enrolled in our study. Out of them 110 were males and 60 were females. 102 were term, 68 were preterm and majority being less than 7 days.

They had varied etiology and clinical diagnosis of birth asphyxia, meconium aspiration syndrome/meconium stained amniotic fluid, neonatal sepsis, neonatal hyperbilirubinemia, respiratory distress syndrome and others (including preterm for nutritional and supportive care, seizures for evaluation, premature rupture of membranes, acute kidney injury, tracheo-esophageal fistula and other congenital malformations).

Neonates were classified according to their gestational age by WHO Fenton charts. Maximum neonates (40.6%) were appropriate for gestational age (AGA). Remaining 17% were small for gestational age (SGA) and 2.4% were large for gestational age (LGA).

Table 1,2 and figure 1 shows that there is a large correlation between the glucometer and lab values when the blood glucose values, as determined by the gold standard is >45mg%. But when the lab values (gold standard) are <45mg% then there is just moderate correlation between the two. The accuracy of glucometer to detect hypoglycemia in newborns in comparison with gold standard (lab glucose oxidase method) is 86.47%.

Method of collection of data: Collection of data was by relevant investigations i.e. glucose estimation by glucometer and laboratory glucose oxidase method.

Methodology: At admission, a detailed history was taken and a thorough physical examination was performed so as to fulfill the inclusion and exclusion criteria laid down in the study protocol.

Capillary blood glucose levels measured using glucometer (ONE TOUCH-select simple)™ with plasma obtained from heel prick using a stylet under aseptic precautions. Simultaneously 2 ml of blood drawn from peripheral vein was collected in fluoride tubes and sent to central clinical biochemistry laboratory for plasma glucose measurement using glucose oxidase method.

The analysis was done on emergency basis within half an hour of collection of blood sample. Routine quality control check was followed for the analysis. A calibrated check using the manufacturer supplied control cuvette was performed once a day on the glucose analyser.

Hypoglycemia was defined as blood glucose levels less than 45 mg/dl Hyperglycemia was defined as blood glucose levels more than 145 mg/dl. Blood glucose levels 45-145 mg/dl was considered as normal. Laboratory value of glucose was taken as gold standard.

Statistical analysis: Statistical methods used were Descriptive Statistics, Frequencies, Contingency Coefficient Test (Crosstabs) and correlation. All the statistical analysis were carried out through the software SPSS for Windows (version 16.0).

Table-1: Diagnostic value of Glucometer in relation to Lab value in detecting the hypoglycemia.

Value	Percentage
Sensitivity	64.40%
Specificity	98.20%
PPV	95%
NPV	83.84%
Accuracy	86.47%

Table-2: Pearson correlation: lab glucose oxidase method and glucometer (capillary sample).

		Lab Glucose Oxidase Method (MG/DL)			Total
		<45	45-145	>145	
Glucometer (Capillary Sample) In MG/DL	<45	38	2	0	40
	45-145	21	100	4	125
	>145	0	1	4	5
Total		59	103	8	170

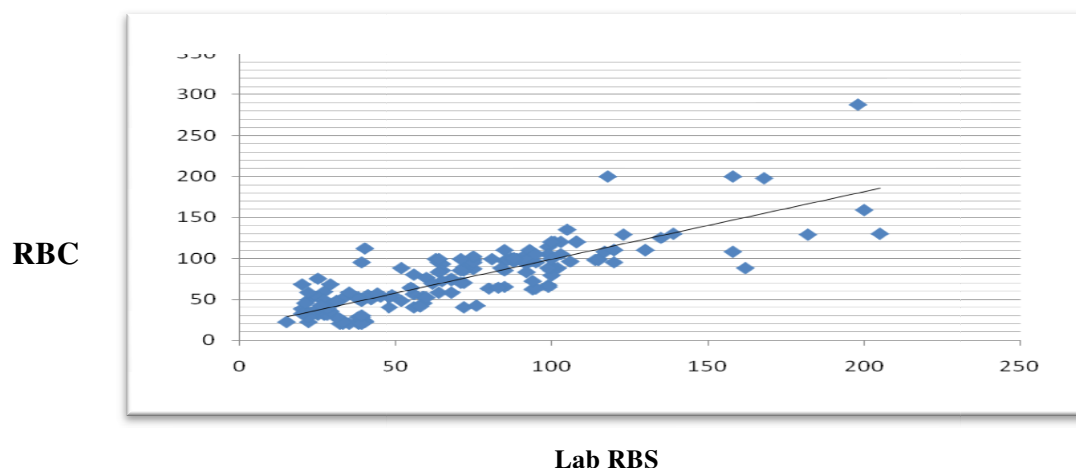


Figure-1: Pearson correlation: lab glucose oxidase and glucometer (Capillary)

◆ RBC
 — Linear {RBC}

Contingency coefficient(r)	p value
+0.837	0.000

Discussion

Neonatal hypoglycemia is a common metabolic disorder and the operational threshold values of blood glucose less than 45 mg/dl should be used to guide management. The normal range of blood glucose is variable and depends upon factors like birth-weight, gestational age, body stores, feeding status, availability of energy sources as well as the presence or absence of disease [19,21]. All “at risk” neonates and sick infants should be monitored for blood glucose levels. In our study we evaluated the efficacy of glucometers in estimating the blood glucose levels in newborns, in comparison with laboratory glucose oxidase method. Main stress was laid on detection of hypoglycemia by both the methods and to know if glucometer is a good screening tool to detect hypoglycemia. Laboratory glucose oxidase method of blood glucose estimation was taken as gold standard. Hypoglycemia was defined as blood glucose level less than 45mg% as defined by the study by Corn lath et al[19]. Our study showed that One Touch (select simple) glucometer had sensitivity of 64.48% to detect hypoglycemia and specificity of 98.20% to detect hypoglycemia which is in correlation with other studies. This

is in accordance with Ngercham S et al[17] and Hamid MH et al[16] respectively (table 3). It was observed from our study that glucometer had a positive predictive value of 95.00% which in contrast to Ngercham S et al[17] and Ho HT et al[14] is low and negative predictive value of 83.84 % which in contrast to Ngercham S et al[17] and Ho HT et al. is low [14] (table 3). The accuracy of glucometer to detect hypoglycemia in newborns in comparison with gold standard (lab glucose oxidase method) is 86.47%.

Table-3: Comparison of sensitivity, specificity, PPV & NPV of various studies.

	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Our study	64.40%	98.20%	95.00%	83.84%
Ngercham S et al [17]	62%	100%	100%	85.7%
Ho HT et al [14]	46.7%	79.2%	73.7%	54.3%

Lab glucose oxidase method is considered as gold standard. Although Glucometers are reported to have several advantages in the analysis of glucose in newborns such as short analysis time, small sample size, quick reading, and can be handled even by unskilled personnel, still it remains as a screening tool. It has been shown that most glucometers are inaccurate at very high or very low glucose concentrations and certain variables like haematocrit, altitude, environmental temperature or humidity and hypoxia may affect the result with bedside testing[15,20]

Correlation of glucometer and lab value: In our study there was good correlation between two methods in the range between 45 mg/dl and 145 mg/dl. It has been shown that most glucometers are inaccurate at very high or very low glucose concentrations and certain variables like haematocrit, altitude, environmental temperature or humidity and hypoxia may affect the result with bedside testing[13,15,17].

In our study glucometer readings were higher in babies having glucose values below 45 mg/dl in relation to laboratory glucose oxidase method. Glucose values measured using laboratory glucose oxidase method was higher in babies who had glucose levels higher than 145 mg/dl when compared with glucometer. We observed that few babies were overestimated for hypoglycemia when tested with glucometer. So keeping in view the high specificity of glucometer in our study, we conclude that, if the clinician feels neonate has hypoglycemia, but the glucometer gives normal values, it is better to get the blood sugar repeated by glucose oxidase method before giving any treatment.

Hence our results agree with previous studies which concluded that glucose reagent strips should be considered only as a easy, rapid, point of care test and not as a diagnostic test, due to their questionable reliability [13,15,18,22]. The limitation of our study was firstly the small sample size in the higher glucose range (>145 mg/dl). Further studies on a larger sample in higher glucose range are needed. Secondly glucose estimation in our study did not specify age in hours at the time of blood glucose estimation. Lastly whole blood glucose level at room temperature in-vitro decline at a rate of 5-7 mg/dl/hour. The use of inhibitors such as fluoride, in collection tubes are used to avoid this problem. The efficacy is best when prepared freshly. But the fluoride tubes used in our study were pre-prepared commercially available tubes.

Conclusion

There is a variable detection rate of hypoglycemia by glucometer in the studies mentioned and also in our study. Glucometer had good correlation at glucose levels 45-145 mg/dl, still its values in this study do not have sufficient validity to replace laboratory testing in diagnosing hypoglycemia and hyperglycemia. We conclude that glucometer test was satisfactory as a easy, rapid, point of care test in diagnosing neonatal hypoglycaemia but it can either over or underestimate glucose results. Although the glucometer had good specificity and negative predictive value, confirmation with laboratory measurements of plasma glucose and clinical assessment of the infant are still of the utmost importance.

What this study adds to our existing knowledge:

Glucometers (point of care devices) as a sole measuring device to screen neonatal hypoglycemia is not satisfactory and confirmation with the laboratory measurements of plasma glucose is still of up most importance.

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