

Comparative study of blood glucose levels in neonates using glucometer and laboratory glucose oxidase method.

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Abstract

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 historically one of the most common metabolic problems seen in both the newborn nursery and neonatal intensive care unit. In neonates, there is not always an obvious correlation between blood glucose concentration and the classic clinical manifestations of hypoglycemia. The absence of symptoms does not indicate that glucose concentration is normal and has not fallen to less than optimal level (40 mg/dl) for maintaining brain metabolism. Present study was conducted on 500 newborns admitted to NICU. Blood glucose levels were measured simultaneously by using glucometer (Accu-chek advantage) and laboratory by using glucose oxidase method. There is a strong correlation between values obtained using both the methods with contingency coefficient-0.7 and p value – 0.000. Accu-chek advantage glucometer had good correlation at glucose levels 40 to 145 mg/dl. Glucometer should be considered only as a screening method, not as a diagnostic test due to their questionable reliability in diagnosing neonatal hypoglycaemia. Although the accu-chek advantage glucometer had good sensitivity and negative predictive value in detecting hypoglycaemia, confirmation with laboratory measurements of plasma glucose and clinical assessment of the infant are still of the utmost importance.

Keywords: Hypoglycemia, Accu-chek advantage Glucometer, Glucose oxidase method.

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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. Metabolic disorders are relatively common in newborn period as compared to any other age group. Hypoglycemia is historically one of the most common metabolic problems seen in both the newborn nursery and neonatal intensive care unit [1, 2]. Symptoms of hypoglycemia in the infants may be subtle. Many other neonatal problems may also cause the signs observed in the infant with hypoglycemia [3]. Symptomatic metabolic disorders (most commonly hypoglycemia and hyperglycemia) are associated with glycosuria with osmotic diuresis, intra-ventricular hemorrhage, increased risk of neuromuscular disability and mental retardation among the survivors. It is therefore essential that all high risk infants should be screened for metabolic disturbances [4].

In neonates, there is not always an obvious correlation between blood glucose concentration and the classic clinical manifestations of hypoglycemia. The absence of symptoms does not indicate that glucose concentration is normal and has not fallen to less than optimal level (40 mg/dl) for maintaining brain metabolism. There is evidence that hypoxemia and ischemia may potentiate the role of hypoglycemia in causing permanent brain damage [3]. Hence frequent monitoring of blood glucose bedside is needed in newborns. The major long-term sequelae of severe, prolonged hypoglycemia are mental retardation or recurrent seizure activity or both. Subtle effects on personality are also possible but have not been clearly defined. Permanent neurologic sequelae are present in more than half of patients with severe recurrent hypoglycemia who are younger than 6 month of age, the period of most rapid brain growth [5-7]. Present study was conducted to evaluate the performance of glucometer (accu-chek advantage) for the detection of blood glucose levels in newborn infants.

Material and Methods

About 500 neonates admitted in Neonatal intensive care unit (NICU) from October 2013 to March 2015 at Basaveshwara medical college Hospital, Chitradurga, were included in the study.

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. Neonates admitted in NICU, were included in the study. Infants >28 days old, neonates shifted to postnatal ward, neonates with PCV less than 40 and more than 70 were excluded from the study.

Capillary blood glucose levels measured using glucometer (Accu-chek advantage) with plasma obtained from heel prick using a stylet under aseptic precautions. Simultaneously 2 ml of blood drawn from peripheral vein was sent to laboratory for glucose estimation using glucose oxidase method. Hypoglycemia was defined as blood glucose levels less than 40 mg/dl (2.2 mmol/L).

Hyperglycemia was defined as blood glucose levels more than 145 mg/dl (8 mmol/L). Blood glucose levels 40-145 mg/dl was considered as normal. Statistical methods used were Descriptive Statistics, Frequencies, Contingency Coefficient Test (Crosstabs), Chi-Square Test. All the statistical methods were carried out through the SPSS for Windows (version 16.0).

Results

In our study group out of 500 neonates, 289 were males and 211 were females. Out of 500 neonates, 377 term babies and 123 preterm babies with mean age of 1 day were studied. Most of the babies were full term appropriate for gestational age comprising 63.6% of our study.

In the present study with lab glucose oxidase method 178 babies showed blood glucose levels less than 40mg/dl, 304 babies had blood glucose ranging from 40-145mg/dl and 18 babies had blood glucose level more than 145mg/dl. With glucometer method 122 babies had blood glucose levels less than 40mg/dl, 362 babies had blood

Table 1. Comparison of incidences of hypoglycemia and hyperglycemia by all the three methods

Blood glucose levels (mg/dl)	Total number of patients		
	Lab glucose oxidase	Glucometer (capillary sample)	Glucometer (venous sample)
<40	178	122	123
40-145	304	362	361
>145	18	16	16
Total	500	500	500

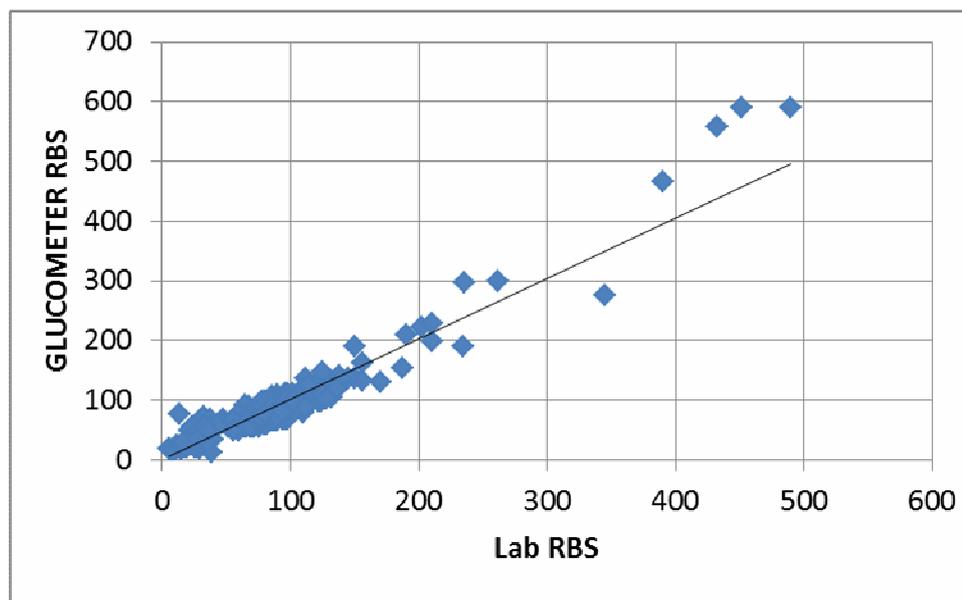


Figure 1. Correlation between glucose values measured using glucometer and lab glucose oxidase method

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

		Lab glucose oxidase method (mg/dl)			Total
		<40	40-145	>145	
Glucometer (capillary sample) in mg/dl	<40	121	1	0	122
	40-145	57	302	3	362
	>145	0	1	15	16
Total		178	304	18	500

Contingency Coefficient - 0.756	p value - 0.000
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There is a strong correlation between values obtained using both the methods.

glucose level ranging from 40-145mg/dl and 16 babies had blood glucose more than 145mg/dl. There was no much difference in the blood glucose levels with capillary and venous blood samples as estimated by glucometer method (Table 1). There is a strong correlation between values obtained using both lab glucose oxidase method and glucometer method using capillary blood with contingency coefficient of 0.756 which is statistically significant with p-value 0.000 (table 2).

Discussion

Neonatal hypoglycemia is a common metabolic disorder and the operational threshold values of blood glucose less than 40 mg/dl (plasma glucose less than 45 mg/dl) should be used to guide management. All “at risk” neonates and sick infants should be monitored for blood glucose levels. Term healthy AGA infants without any risk factors need not be monitored routinely. Evaluation of efficacy was based on detection of hypoglycemia and hyperglycemia by both the methods and to know if glucometer can be used as a screening tool to detect abnormalities in blood glucose levels in neonates. Laboratory glucose oxidase method of estimation of blood glucose estimation was taken as gold standard. Accu-chek advantage was specifically recommended by their manufacturers for use in neonates.

Of the 500 neonates screened for plasma blood glucose, 178 (35.6%) were hypoglycemic. The incidence was comparable with other studies. Anderson et al[8] reported 38% incidence, Arun kumar de et al [9], reported 32.67% incidence. The incidence of hypoglycemia as measured by accu-chek advantage with capillary sample was 123 (24.6%) and with venous sample were 122 (24.4%). In our study incidence of hypoglycemia among term babies was 121 (32.3%) and among preterm babies was 57 (45.6%), as compared to 81 (21.6%), 45 (32.8%), 83 (22.1%), 40 (32%) with accu-chek advantage with capillary and venous sample respectively. Arun kumar De et al[9] quoted the incidence of hypoglycemia as 29.95% in term babies and 77.77% in preterm babies. Inayatullah Khan et al[10] found hypoglycemia in 29% of term and

32.3% of preterm babies. Overall incidence of hypoglycemia was more in preterm babies compared to term babies and is comparable with other studies.

Our study showed that accu-chek advantage glucometer had sensitivity of 86.17% to detect hypoglycemia and specificity of 99.19% to detect hypoglycemia which is in accordance with Hamid MH et al[11] (sensitivity 98% and specificity 93%) and Mehta et al (sensitivity 86% and specificity 89%) [12]. It was observed from our study that glucometer had a positive predictive value of 70.28 which is in contrast to Ho HT et al[13] and Ngermcham S et al[14] is low and negative predictive value of 99.6% which in contrast to Ho Ho et al[13] and Ngermcham S et al[14] is high. The accuracy of glucometer to detect hypoglycemia in newborns in comparison with gold standard (lab glucose oxidase method) was 66%.

In our study there was good correlation between two methods in the range between 40 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. In our study glucometer readings were higher in babies having glucose values below 40 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. This overestimation could have detrimental consequences because glucose values were lower in these babies when tested simultaneously using laboratory glucose oxidase method. Glucose values were underestimated with glucometer in higher range when compared with laboratory glucose oxidase method.

These findings suggest that at very low and high glucose readings, glucometer can either over or underestimate glucose results. Similar results was found when glucose values estimated by glucometer using venous sample. The Acu-chek Advantage glucometer usually overesti-

mated plasma glucose <40 mg/dl and underestimated plasma glucose values >145 mg/dl. So it is good practice to confirm low and high glucometer readings with laboratory before giving any treatment. And hence our results agree with previous studies which concluded that glucose reagent strips should be considered only as a screening test, not as a diagnostic test, due to their questionable reliability

Conclusion

Accu-chek advantage glucometer had good correlation at glucose levels 40-145 mg/dl. Glucometer should be considered only as a screening method, not as a diagnostic test due to their questionable reliability in diagnosing neonatal hypoglycaemia. The glucometer values in this study do not have sufficient validity to replace laboratory testing in diagnosing hypoglycemia and hyperglycemia. Although the accu-chek advantage glucometer had good sensitivity and negative predictive value in detecting hypoglycaemia, confirmation with laboratory measurements of plasma glucose and clinical assessment of the infant are still of the utmost importance.

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