Original Article

Validity of glucose measurements in the blood by a glucometer reagent strip in critically ill infants

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ABSTRACT

Introduction: Hypoglycemia in critically ill infants is a frequent metabolic disorder which is often due to defective glucose homeostasis. If not recognized annotated early, it can result in severe neurological damage with high mortality and morbidity. Today, glucometer is recommended for fast measuring blood glucose. The aim of this study was to evaluate the accuracy of glucometer for early diagnosis of hypoglycemia in the acutely ill infant.
Materials and methods: This study evaluates 130 critically ill infants less than 1year of age who were admitted to Besat hospital − Sanandaj − IRAN. Blood sugar was measured by standard serum method (glucose oxidase) and glucometer reagent strip.
Results: The overall means of blood sugar were 115.6 ± 1.75 with serum method and 119.1 ± 1.56 with glucometer method. The rates of sensitivity, specificity, positive predictive value and negative predictive value with glucometer method and with serum glucose method were 72%, 53%, 62%, and 77% respectively. The correlation between the two methods was significant ($p < 0.001$). Kappa statistics for the two methods was 42%.
Conclusions: The results showed that in general, glucometer may be appropriate for rapid screening in emergency situations and when frequent blood glucose monitoring is needed but it cannot be regarded as a very suitable and reliable tool for diagnosis of hypoglycemia in critically ill infants.

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1. Introduction

Hypoglycemia is a common metabolic disorder in the critically ill infant which refers to the serum level of less than 55 mg/dL [1].I t is more common in premature and low birth weight infants. The prognosis of infants with hypoglycemia depends on early recognition and appropriated management [1,2]. Unrecognized hypoglycemia may lead to death or severe defects and long-term neurological damage in infants [3,4]. The standard method of measuring blood glucose is glucose oxidase. Since this method is usually done in the main laboratory, prompt results for timely and appropriate treatment are not available. Furthermore obtaining blood in infants is difficult and may damage to infant's vessels and need to a great volume of blood [5]. Thus, a reliable and real-time control device is needed for early detection and treatment [6].

Therefore, glucometer is widely used for measuring the concentration of blood glucose in the pediatric intensive care unit and a neonatal intensive care unit [7]. Glucometer was originally designed for self-monitoring of patients with diabetes mellitus [8]. Glucometer, like other medical devices, has certain limitations so that the performance and accuracy of the obtained results are influenced by multiple factors such as operator interference, patient's condition and medicines, type of used sample, sampling method and body metabolism [9]. Although the measured values by glucometer in the range of normal and high blood sugar are similar to those obtained in the laboratory (glucose oxidase), these values are less investigated in the range of low sugar levels (hypoglycemia).

This study was carried out to investigate the findings of blood glucose measurements by glucometer and standard laboratory method in critically ill infants under one year old, admitted in pediatric intensive care unit at Besat Hospital in Sanandaj-Iran.

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2. Materials and Methods

One hundred thirty consecutive blood samples were tested in critically ill infants less than 1 year of age with the mean age of 7.4 months (range from 2 to 12 months) who were admitted to the pediatric intensive care unit of Besat Hospital at Sanandaj-Iran due to a bad general condition. Need to blood sugar measurement was according to clinical diagnosis. It is obvious that patients who had hormonal or metabolic disorder were excluded from the study. Each blood sample glucose was tested simultaneously for glucose concentration with glucometer and strip test (accua-chek) and with a standard method (glucose oxidase). Measurements were made by a single observer (a registered nurse) as indicated within 10 min of blood collection.

Then the results of glucometer measurements were analyzed and compared with the data obtained from serum method (Gold standard) by linear regression and the Spearman rank correlation coefficient. The optimal cut-off point on the graph was equal to 60 mg/dL so that for fasting blood glucose it was less than or equal to 60 mg/dL. The area under the curve for glucometer was 0.779. Sensitivity, specificity, positive predictive value and negative predictive value were calculated using a glucometer to be compared with the standard method. In order to check the consistency between the two methods, the Kappa agreement was used. The data were analyzed using SPSS 20 and Stata12 software. The significance level in this study was considered as $P < 0.05$. This study was approved by the Research Ethics Committee of Kurdistan University of Medical Sciences, Sanandaj, Iran.

3. Results

This study was conducted on 130 patients with 2–12 months old (average 7.4 ± 2.7). 74 patients (57%) were male, 56 patients (43%) were female. The results showed that the standard measure of blood sugar was higher than the glucometer method, but the difference was not significant ($P = 0.176$) (Table 1). The results also showed that there was a significant correlation between glucometer and standardized measurement method ($P < 0.001$) (Table 1, Fig. 1). ROC curve analysis showed that the accuracy of blood sugar measurement by glucometer for diagnosis of hypoglycemia was 77%. The optimal cut-off point on the graph was equal to 60 mg/dL, so that for blood glucose level less than or equal to 60 mg/dL, total sensitivity and specificity were 72% and 53%, respectively (see Tables 2 and 3).

Table 1
The mean of blood glucose levels with Glucometer and Standard laboratory [n = 130].

Category/Infant	Mean $\pm$ SD[a]	Confidence Interval (CI)	P-Value
Standard	155.2 ± 99.4	(128.1−282.3)	0.176
Glucometer	$121.7.7 \pm 61.8$	(107.6−135.8)	

[a] SD: Standard Deviation.

Fig. 1. Correlation between glucometer and standard laboratory method.

Table 2
Pearson correlation between Glucometer and Standard laboratory [<60 mg/dL, n = 130].

Measurement Method	Number (%)	Pearson Correlation	P-Value
Standard (<60 mg/dL)	17 (13.1)	0.781	<0.001
Glucometer (<60 mg/dL)	22 (16.9)		

4. Discussion

The management of blood sugar level within the normal range is very important to reduce the complications and duration of hospitalization of the patients and glucometer is one of the ways to control blood sugar in patients. In this study, the mean blood glucose value in infants measured by standard method was more than glucometer. According to the study conducted by Sreenivasa et al. [8], the difference between the results was expressed in very high and very low concentrations of blood sugar. Sreenivasa et al. [8] explain that glucometer results in very low and very high blood sugar concentrations are variable and unreliable also results may be affected by some conditions such as hematocrit, altitude, temperature or humidity, and hypoxia.

The results of our study showed levels of 72% sensitivity, 53% specificity, 62% positive predictive value and 77% negative predictive in the test of infants blood sugar. Kappa statistic obtained in our study between the two methods was 42%. In this study, in ROC curve analysis, blood glucose measurement with glucometer method is relatively high-accurate for measuring of blood glucose, and the optimal cut-off point is calculated as 60 mg/dL. For the blood glucose less than or equal to 60 mg/dL, sensitivity and specificity were 72% and 53%, respectively which indicated moderate sensitivity and specificity.

Based on these results, although glucometer can have suitable efficacy for capillary blood sugar monitoring, with regard to special settings of each one of the devices in the manufacturing factories, it seems that there are always differences between them and the common laboratory methods in the hypoglycemic situation.
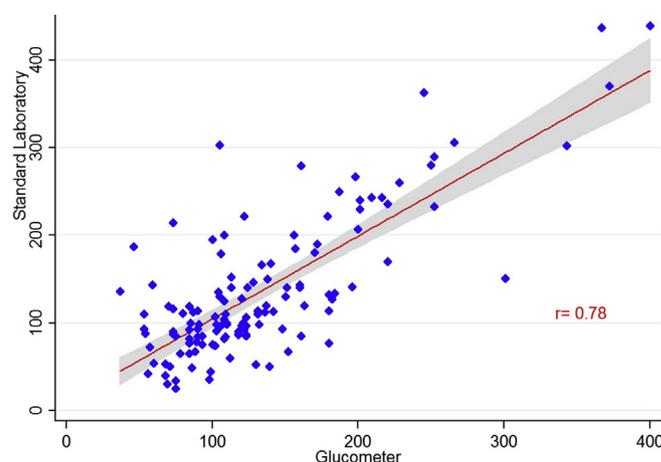
Table 3
Sensitivity, Specificity, [a]PPV and [b]NPV of glucometer readings of blood glucose level in infant.

Category	Sensitivity(CI)	Specificity(CI)	PPV(CI)	NPV(CI[c])	Kappa (%)
Infant	72 (63.4−80.2)	53 (45.4−61.6)	62 (54.7−69.3)	77 (70.1−85.3)	42

[a] PPV: positive predictive value.
[b] NPV: negative predictive value.
[c] CI: Confidence Interval.

One of the limitations of this study was lack of other devices with different brands, so that if there were other devices to measure blood glucose, their accuracy could be compared with each other and more accurate results could be achieved.

5. Conclusion

We were interested to learn how readings were done by a glucometer reagent strip test in blood from severely ill infants correlated with values determined by standard methods. Analysis of data obtained indicates that the two methods offer similar precision with a high degree of accuracy in sick infants with blood glucose concentrations >60 mg/dL. The findings suggest that the determination of blood glucose by mean of a glucometer reagent strip is an easy bedside procedure and provides similar information more quickly and more easily than the traditional method of assessing the blood glucose levels. Another advantage of using glucometer reagent test is the small volume of sample required to measure blood glucose level. A simple reliable method for determining the glucose concentration of the blood is now available. The small volume of blood required makes the glucometer test strips particularly more useful in infants requiring intensive care. There are tangible differences between the accuracy of brands of glucometer performances which should be determined in large volumes with the help of comparative surveys of laboratory standards so that more accurate and safer glucometer can be ultimately introduced to critically ill infants for daily monitoring and measurement of blood sugar.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.dsx.2018.11.003.

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