

Blood Glucose Measurement by Glucometer in Comparison with Standard Method in Diagnosis of Neonatal Hypoglycemia

Fatemeh Nayeri¹, Mamak Shariat¹, Hamid Modarres Mousavi Behbahani¹,
Padideh Dehghan¹, and Bita Ebrahim²

¹ Family Health Institute, Maternal- Fetal & Neonatal Research Center, Tehran University of Medical Sciences, Tehran, Iran

² Family Health Institute, Breast Feeding Research Center, Tehran University of Medical Sciences, Tehran, Iran

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Abstract- Hypoglycemia is considered as a serious risk factor in neonates. In the majority of cases, it occurs with no clinical symptoms. Accordingly, early diagnosis is extremely imperative, which can also lead to less morbidity and mortality. The aim of this study was to assess the importance of screening blood glucose using glucometer (known as a quick and cost-effective diagnostic test) in comparison with laboratory method. A total of 219 neonates at risk of hypoglycemia were included in this study. Blood glucose was measured by glucometer and laboratory. In addition glucose level of capillary blood was measured by glucometer at the same time. Sensitivity and specificity of capillary blood glucose measurement by glucometer were 83.5%, 97.5% respectively (ppv=80%), (npv=98%). Capillary blood glucose measured by glucometer has an acceptable sensitivity and specificity in measurement of neonatal blood glucose. Therefore measurement by glucometer is recommended as a proper diagnostic test.

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Introduction

Hypoglycemia is one of the most prevalent metabolic disorders causing emergency problems in neonates (1). Fetus provides 60 - 70 % of its energy intake from placenta along with glucose existing in maternal blood; as a result blood glucose level in fetus is two thirds of the mother's. After birth the main source of glucose supply is cut off.

Consequently glucose should be supplied by glucogenolysis of liver storage, gluconeogenesis and through breast feeding (1). Blood glucose less than 40mg/dl during the first 24 hours of birth is a criterion for hypoglycemia (2).

In case of delayed onset of nutrition, in 10 % of neonates' blood glucose level will not go above 30mg/dl (2,3).

Also 16% of LGA and 15% of SGA neonates are hypoglycemic during the first few days of birth (1). Neonates weighing less than 2500gr or more than 4000gr, premature neonates, neonates born to diabetic mothers, IUGR (Intra Uterine Growth Retardation) neonates or SGA (Small for Gestational Age), neonates

affected by sepsis, asphyxia or born to mothers taking hypoglycemic oral agents or beta – adrenergic drugs are at high risk of hypoglycemia (3). Complications which can be caused by hypoglycemia includes: nervous system damage followed by learning, intelligence and developmental disorders, epilepsy, mental retardation, white matter disorder (cerebral bleeding or infarction) nervous system development disorder, cerebral palsy and motor disorders (spasm in extremities and/or ataxia) (3).

Therefore, routine and intermittent blood glucose screening is necessary to detect hypoglycemia in each one of high risk neonates (even though asymptomatic). However, in some nurseries capillary blood glucose is monitored by glucometer through screening and in case of low capillary blood glucose or symptoms of hypoglycemia, level of blood glucose is confirmed by laboratory test. As expected laboratory measurement should be made promptly. If blood sample is not delivered to the laboratory immediately, glucose level will drop 15-20 mg per hour (3,4).

It is noteworthy that not many nurses are expert at taking blood samples of neonates and in nurseries where

Corresponding Author: B. Ebrahim

Family Health Institute, Breast Feeding Research Center, Tehran University of Medical Sciences, Tehran, Iran
Tel: +98 21 61192357, Fax: +98 21 66591315, E-mail address: bitaebrahim@yahoo.com

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screening is not routine, a good number of samples are arterial which may result in traumatized arteries. Aside from emotional and mental pressure, heavy cost of medical care is also imposed on parents. On the other hand, there are several setbacks in connection with transferring samples to the laboratory and doing the tests promptly.

One of the most important reasons for replacing laboratory test of blood glucose is to use a cost-effective method, considering that the majority of lab tests are expensive. In this study authors aimed to evaluate sensitivity and specificity of glucometer as a diagnostic test in neonates at risk of hypoglycemia by measuring blood glucose concentration with glucometer and laboratory test at the same time.

Materials and Methods

According to a study conducted by Hamid MH (6), in which glucometer was considered to have 98% sensitivity in diagnosis of hypoglycemia, with 0.5% error 95% confidence interval, in this test-comparative study blood glucose of 219 neonates was monitored. A total of 219 blood samples of neonates at risk of hypoglycemia were studied in Resalt hospital in Tehran from April 2010 to April, 2011.

Current study was approved by the scientific and ethics' committee of research deputy of Tehran University of Medical Sciences.

Inclusion criteria were as follows : neonates over 4 kg , less than 2.5kg , less than 37 weeks of gestational age , suspected neonatal sepsis, history of asphyxia , born to women using beta – adrenergic drugs for any reason and presence of symptoms of hypoglycemia .All neonates were visited by specialists.

According to the inclusion criteria neonates were included in the study, and based on the protocol, blood samples were taken by a trained nurse within 2, 6, 12, 24 hours after birth. Two ml of arterial blood was sampled, a drop of which was applied to the test strip, Accua-chek (Roche), and then it was placed inside the device while glucometer was on a flat surface.

Subsequently in 10 seconds, level of blood glucose appeared on the display.

The remainder of blood was kept in ice and immediately sent to the laboratory where blood glucose concentration was measured by photometric analysis and glucose oxidase. Accua- chek active glucometer

made by Roche Company was used.

A drop of blood was applied to a chemically active disposable test strip on which the chemical reaction occurred due to the action of glucose deoxyreductase that resulted in color change. Glucometer verified this color change and showed glucose level.

At the same time, a drop of capillary blood, (drawn from the heel) was sampled and applied to the test strip to measure level of glucose. Before sampling, the heel was warmed up by hand massage followed by disinfecting the spot, and then blood sample was taken.

In this study gold standard was serum glucose measurement in the laboratory by means of using quantitative diagnostic kit to measure glucose in serum by photometric analysis and glucose oxidase method.

Blood glucose level less than 40mg/dl during the first two hours of birth and less than 45mg/dl during the same day was considered as hypoglycemia (2).

Statistical analysis

Data were collected and recorded in SPSS software, Version 15, and analyzed by X2 statistical tests (under supervision of a statistics expert). Then correlation between levels of glucose measured by laboratory method and blood glucose of arterial and capillary samples monitored by glucometer was evaluated. Also sensitivity, specificity and predictive values were defined according to data.

Sensitivity of glucometer would be proficient to respond to this question "Among all hypoglycemic neonates, how many of them are detected hypoglycemic by glucometer?" Specificity of glucometer would reply to this question: "Among All normoglycemic neonates, how many cases are detected normoglycemic by glucometer?" positive predictive value (PPV) refers to probability of real positive of a positive result in analysis of diagnostic value of a test, PPV is the most valid criterion. P-value<0.05 was considered significant in this study.

Results

During one year period (April, 2010 – April, 2011), level of glucose was monitored in 219 blood samples of neonates at risk of hypoglycemia.

Table 1 shows neonates' general characteristics (birth weight, maternal age, gestational age). Of 219 neonates, 108 (49%) were female and 111 (51%) were male.

Table 1. General characteristics of neonates, A total of 111 (51%) neonates were male.

Birth weight	*3070.54 ± 555.25 gr
Maternal age	29.81 ± 4.89 ys
Gestational	39.81 ± 1.08 week

*Data are presented as mean ± standard deviation

Blood glucose measurement was performed by three methods on all neonates. Level of blood glucose measured by laboratory method varied from 15 to 229 mg/dl (64.24 ± 60) level of arterial blood glucose monitored by glucometer ranged from 20 to 263mg/dl (45.59 ± 73) and capillary blood glucose ranged from 30 to 275 mg/dl (68.65 ± 65).

In each group, 24 (11%), 13(6%) and 25(11%) neonates were hypoglycemic. Totally, of 24 hypoglycemic neonates detected by laboratory method, 12 and 20 of them were also hypoglycemic by arterial blood and capillary blood glucometer monitoring, respectively. Four hypoglycemic neonates were

diagnosed only by laboratory method and five were diagnosed only by glucometer.

Considering laboratory method as gold standard, sensitivity and specificity of capillary blood glucose measurement by glucometer were 80% and 97.5%, respectively (PPV: 80% NPV: 98% (P: 0.0001). While arterial blood sample glucometry showed 50% sensitivity and %99.5 specificity, PPV and NPV were 92.5% and 94% respectively (P: 0.0001).

In table 2 sensitivity and specificity of glucometer method are shown. It is necessary to point out that no complication was caused by heel capillary sampling.

Table 2. Sensitivity and specificity of glucometer method (capillary blood sampling)

Laboratory method	Hypoglycemia Number (%)	Normoglycemia Number (%)	Total number
Hypoglycemia	20 (83)	5 (2.5)	25
Normoglycemia	4 (17)	190 (97.5)	194
Total	24 (100)	195 (100)	219

Sensitivity: 83% (20/24), Specificity: 97.5% (190/195), PPV: 80% (20/25), NPV: 98% (190/194)

Discussion

Since hypoglycemia is considered a serious threat for neonates, using a quick cost-effective and reliable test is of high value. In this study, hypoglycemia was detected in 24 (11%) samples by laboratory test and 25 (11%) samples of capillary blood glucose by glucometer which is suggestive of concordance between the two methods.

Capillary blood glucose monitored by glucometer had 83% sensitivity and 97.5% specificity in comparison with laboratory standard test.

These figures indicate that measuring blood glucose by glucometer is an appropriate test because it has high sensitivity and specificity enabling us to detect few existing cases of the disease.

Above and beyond, this test helps reducing the number of individuals with false positive results. Capillary blood glucose monitoring by glucometer is a reliable test to diagnose or even rule out neonatal hypoglycemia.

Moreover, Capillary blood glucose monitoring by glucometer has the following characteristics to be applied as an appropriate screening test: quick

performance within a few minutes, least required preparation, and no risk for the patient and acceptable for parents as well as its cost-effectiveness.

In addition, positive predictive value of this test is 80%, which indicates patients with real positive test result and its negative predictive value of 98% suggesting the value of this test in predicting absence of the disease.

On the other hand, results of monitoring arterial blood glucose by glucometer indicated 92% of PPV and 94% of NPV. Despite good specificity, this test does not have high sensitivity and is simply performed to evaluate its concordance with standard laboratory test. So this test will not be practically applied to monitor blood glucose. However, in most of the previous studies such as Elusiyani JBE's (4) a similar method was applied to evaluate sensitivity and specificity of glucometer, in which the former and latter were reported to be 96% and 95%, respectively.

Conversely in this study, capillary blood glucose (taken from the heel) by glucometer was evaluated, since in neonatology arterial blood sampling for glucometry is not a routine procedure. As a matter of

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fact, capillary blood glucose measurement was not applied in earlier studies.

Elusiyan JBE study was conducted to evaluate sensitivity and specificity of glucometer on children referring to emergency room. In HOHT's study (5), which is somehow similar to current one, although glucometer detected more cases of hypoglycemia, its sensitivity was 92% and NPV: 90%. In a study by Hamid MH (6) on neonates at risk of hypoglycemia, glucometer showed 98% sensitivity, 93% specificity and PPV was 88% in diagnosis of neonatal hypoglycemia. As a result, glucometer can be recommended for screening.

According to Gleeson's point of view, glucometer is considered as a practical device in paediatrics (7).

Morey also estimated sensitivity and specificity of glucometer to be 95% and strongly recommended this method as the most appropriate test to evaluate hypoglycemia in emergent cases in pediatrics (8).

Although Morey study was not conducted on neonates, the important point is that criterion for hypoglycemia in infants is at higher levels than neonates. However, few studies approve testing by glucometer as a sensitive and specific method for checking and determining lower level of blood glucose.

In present study the authors deliberately compared three methods to decrease probability of error because of capillary blood glucose monitoring by glucometer. Glucometer is recommended as an appropriate screening test for hypoglycemia in neonates.

Given heavy work load of nurses and laboratory personnel as well as heavy cost of lab tests and parents' concern about repetitive sampling, monitoring of blood glucose by glucometer in neonates is strongly advisable (9).

Measuring capillary blood glucose (on the heel) by glucometer has adequate sensitivity and specificity in evaluation of blood glucose in neonates. Thus, laboratory test can be replaced with this method as an appropriate diagnostic test. However, more studies by

means of larger sample size are recommended to evaluate more sensitive types of glucometers.

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