Evaluation of the Bedside Glucose Monitoring System in Neonatal Units

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Abstract

Objective : To evaluate the performance of a commercial® reader compared with a laboratory method in neonates with a variety of diseases and conditions.

Patients and Method : A total of 175 patients were included in the present study. Venous whole blood samples were analyzed with a commercial® reader by trained nurse. Through the same sampling site, specimens were collected, spun and plasma were sent to the laboratory for measurement of plasma glucose.

Results : The regression analysis between the results of a commercial® reader and laboratory glucose were significantly correlated ($r = 0.97$; $p < 0.001$) with the result as follows: A commercial® reader = Laboratory glucose - 0.17 ($n = 175$). A positive slope of 0.04 was found between hematocrit and difference between a commercial® reader and laboratory plasma glucose. However, this correlation was of little clinical significance.

Conclusions : A commercial® reader showed a good correlation with the standard laboratory method for the measurement of plasma glucose in neonates with a variety of diseases and conditions.

Key word : A Commercial® Reader, Neonatal, Blood Glucose, Hypoglycemia, Hyperglycemia

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® Medisafe Reader [Terumo (Thailand) Co., Ltd.]

Neonates experience wide fluctuations in blood glucose as a consequence of a variety of diseases and conditions[1]. Newborn infants requiring intensive care need frequent determinations of blood glucose and rapid blood glucose testing by a glucose meter for monitoring blood glucose levels to prevent adverse effects associated with hypo and hyperglycemia. Unfortunately, glucose meters have been designed and optimized for measurement only in adults. Studies in the past have shown that glucose meters gave unpredictable results and should be used with caution in neonatal units[2,3]. The necessity to rely on the rapid glucose testing has prompted manufacturers to develop a new system to overcome the problems. The use of these devices would save time in the monitoring of neonatal blood glucose and would improve care.

The purpose of the present study was to evaluate the accuracy of the glucose reader commercially available compared with a laboratory method in neonates with a variety of diseases and conditions.

PATIENTS AND METHOD

From 1 August 2002 to 30 September 2002, the authors determined in a cross sectional study in the neonatal ward of Nakhon Ratchasima Hospital, the blood glucose concentration of 175 infants at different times after delivery. Of these, 111 were patients who were admitted to the neonatal ward for a variety of reasons and 64 were normal infants who were born with a birth weight less than 2,250 grams or more than 4,000 grams.

Assigned nurses and laboratory technologists were trained how to use a commercial reader before the beginning of the study. Each of them performed triplicate assays of the glucose control solutions (low, normal, and high) to familiarize themselves with the meter, reagents, and proper testing technique. The laboratory comparative methods, the HITACH912, using the manufacturer's reagents were assessed for precision and accuracy. Routine quality control data were checked each week to certify the internal coefficient of variation (CV) of less than 5 per cent. The infants were included only if a blood specimen was to be drawn during the course of their normal medical care. When a sample was taken for routine medical care, the attending nurse performed a venous whole blood glucose measurement with a commercial reader and collected an additional 500 μl of whole blood in a sodium fluoride micro collection container for laboratory glucose (in duplicate). The specimens were centrifuged immediately (5 min at 5,000 rpm in a microcentrifuge) in the nursery ward and transported to the laboratory. Hematocrit (Hct) was also determined in the same setting. Samples were excluded if the Hct was less than 20 per cent or more than 60 per cent as recommended by the manufacturer.

Ethical approval for the study was granted by the ethical committee of Nakhon Ratchasima Hospital.

Statistical analysis

The means and standard deviation of venous whole blood glucose levels determined by a commercial reader were compared with plasma glucose from the same site determined by the standard reference instrument results. The correlation of blood glucose levels between a commercial reader and the reference instrument measurement was studied using SPSS V9.01 for windows.

RESULTS

One hundred and seventy-five sample sets were collected from 111 patients in the NICU and 64 newborn infants with a mean gestational age of 33.9 weeks and a mean birth weight of 2,415 g (range 1,100-4,600 g). Plasma glucose results varied from 1.4 to 28.5 mmol/L and the Hct results varied from 21 per cent to 60 per cent (mean 45.2% $\pm$ 8.9%). The results obtained by a commercial reader and measured venous whole blood glucose concentration and plasma glucose levels from the laboratory methods showed that the correlation coefficient was 0.97 ($p < 0.001$). A linear regression analysis resulted in the following (Fig. 1)

A commercial reader = Laboratory glucose - 0.17 (n = 175).

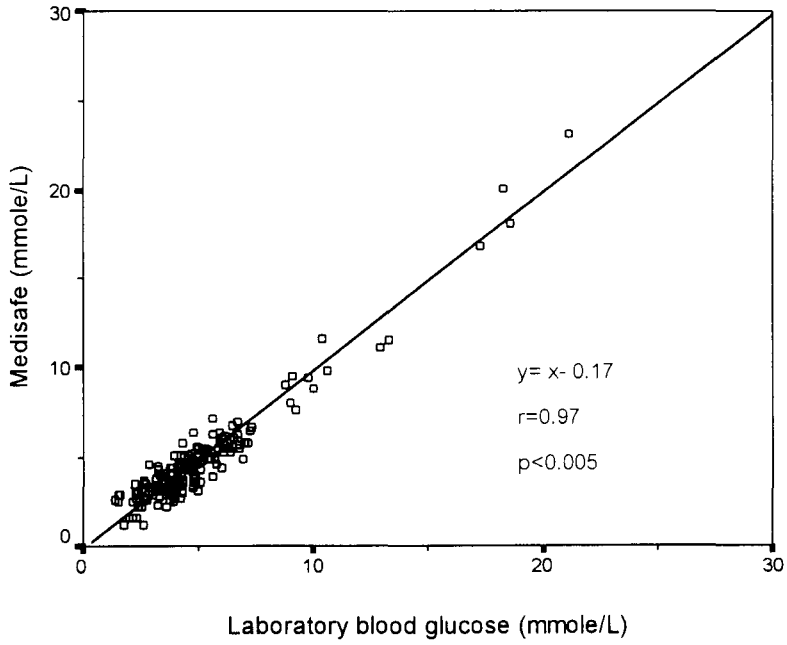

Fig. 1. Regression analysis of the results from a commercial reader and those obtained from standard laboratory methods.

Possible interference from Hct on the glucose levels measurement with a commercial reader was evaluated. Assuming the laboratory method had no interference from Hct, a plot of the Hct values as a function of the difference between the laboratory methods and glucose meter results was made (Fig. 2). A positive slope of 0.04 and y-intercept of -1.4 was obtained ($r = 0.38$; $p < 0.05$).

DISCUSSION

In humans, glucose is the primary source of energy. Variation of blood glucose levels is a common problem in neonatal intensive care. Aggressive diagnostic and treatment is recommended to prevent severe consequences from abnormal glucose levels[4]. Prolonged hypoglycemia increases the risk of neurologic dysfunction[5] including permanent neurological and developmental delays. Seizures, when they occur secondary to hypoglycemia are associated with an especially poor neurologic prognosis. In the opposite direction, significant elevation of blood glucose is associated with intracranial hemorrhage, increased mortality, and developmental delay[6]. Causation of these sequelae is unclear. One possibility is that hyperglycemia results in osmolarity changes that may disrupt cellular function. Additionally, premature infants have a limited ability to regulate glucose, even when it is exogenously supplied. High rates of glucose and lipid infusions, the use of caffeine or theophylline and gram negative sepsis are also associated with a higher incidence of hyperglycemia.

Rapid identification and treatment of glucose abnormalities is crucial in the prevention of potentially devastating neurological injury in neonates. Preterm neonates and the critically ill are at high risk for glucose abnormalities. Bedside testing for blood glucose obviates the need to wait for laboratory results, facilitating prompt clinical management to prevent adverse effects from hypo and hyperglycemia.

A good system for point of care testing is necessary for such a prompt evaluation and management. The blood glucose monitoring system must be accurate, precise, versatile and rapid enough for the physician to decide on the appropriate treatment.

Accurate and reliable estimation of blood glucose is an essential component of the care received by newborn babies admitted to special care baby units. Plasma glucose measured by the standard laboratory

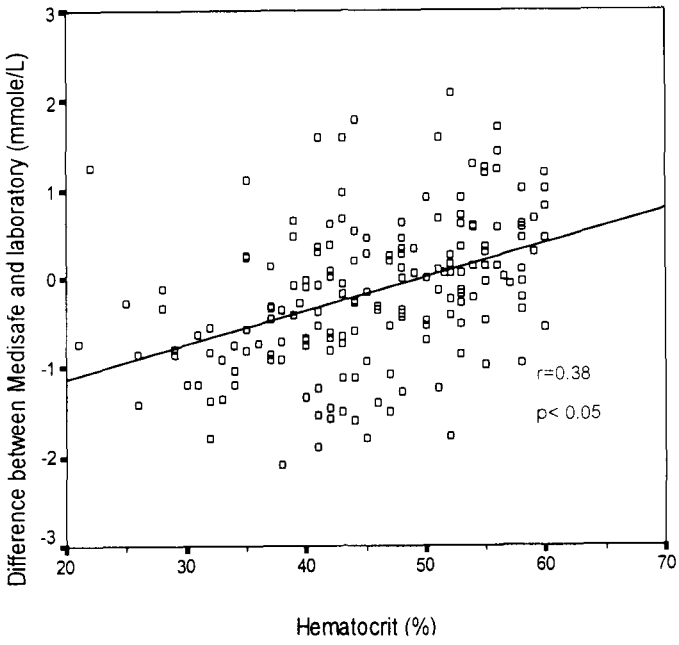

Fig. 2. Effect of hematocrit on plasma glucose differences between the results of a commercial reader and those of the laboratory methods.

technique is more reliable but delays are inevitable in general practice. Even preservative agents to inhibit glycolysis such as sodium fluoride are still inefficient. Glucose decay rates (0.3-0.34 mmole/L or 5.4-6.1 mg/dl) over the first hour[7]. Another plausible explanation for inaccuracy may be due to skin cleaning substances such as isopropyl alcohol which may result in falsely high capillary readings[8,9]. The present study design was to eliminate inaccuracy due to these problems. In neonates, most pediatricians usually use venous whole blood glucose determined by a glucose reader or meter as a tool for blood glucose evaluation. However, its accuracy is still questionable. Therefore the authors designed the study to match the ordinary use of a glucose reader in everyday pediatrician practice. Another problem encountered was the confounding of Hct to the glucose reader. The present study showed that overestimation of blood glucose happened in high Hct levels. However, the effects were clinically negligible. A good technique for both blood collection and glucose readings is needed to avoid all of these problems.

The present result shows that a commercial glucose reader is accurate and reliable for bedside glucose monitoring in a variety of diseases and conditions in neonates. Even with other problems such as inadequate regional perfusion and local metabolic disturbance, the reader still gave comparable results compared with the standard reference method. However, caution in interpretation of blood glucose results is needed when testing a sample with too high or too low Hct values. Following the manufacturer's recommendations by using the reader in the recommended range can minimize the problems.

The present study was conducted in a general hospital and in a general practical way for the purpose of generalization. However, accuracy and precision of the tests depends on adequately trained personal, method of collecting specimens and quality control of the meter.

In conclusion, the present results showed a good correlation between a commercial reader and the laboratory comparative method for the measurement of plasma glucose in neonates with a variety of diseases and conditions. Therefore, a commercial reader system can be helpful in a neonatal setting for the monitoring of blood glucose levels in most cases.

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REFERENCES

1. McNamera PJ, Sharief N. Comparison of EML 105 and advantage analysers measuring capillary *versus* venous whole blood glucose in neonates. Acta Paediatr 2001; 90: 1033-41.
2. Lin HC, Maquire C, Oh W, Corvett R. Accuracy and reliability of glucose reflectance meters in the high-risk neonate. J Pediatr 1989; 115: 998-1000.
3. Taylor HM, Mujoomdar A. Bedside testing of the blood glucose level in neonates: What to use? Can Med Assoc J 1990; 142: 802.
4. Kalhan S, Peter-Wohl S. Hypoglycemia: What is it for the neonate? Am J Perinatol 2000; 17: 11-8.
5. Lucas A Morley R, Cole TJ. Adverse neurodevelopmental outcome of moderate neonatal hypoglycemia. BMJ 1988; 297: 1304-8.
6. Louik C, Mitchell AA, Epstein MF, Shapiro S. Risk factors for neonatal hyperglycemia associated with 10 per cent dextrose infusion. Am J Dis Child 1985; 139: 783-6.
7. Chan AY, Swaminathan R, Cockram CS. Effectiveness of sodium fluoride as a preservative in blood. Clin Chem 1989; 35: 315-7.
8. Grazaitis DM, Sexson WR. Erroneously high dextrostix values caused by isopropyl alcohol. Pediatrics 1980; 66: 221-2.
9. Togari H, Oda M, Wada Y. Mechanism of erroneous dextrostix readings. Arch Dis Child 1987; 62: 408-7.

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วัตถุประสงค์ : เพื่อประเมินผลในการใช้เครื่องอ่านระดับน้ำตาลที่มีจำหน่ายชนิดหนึ่ง® เปรียบเทียบกับผลทางห้องปฏิบัติการในเด็กทารกแรกเกิดที่มีภาวะและโรคต่าง ๆ

ผู้ป่วยและวิธีการ : ผู้ป่วยทารกแรกเกิดจำนวน 175 คน ได้รับการเจาะตรวจระดับกลูโคสจากเส้นด้วยเครื่องอ่านระดับกลูโคสที่มีจำหน่ายชนิดหนึ่ง® โดยพยาบาลที่ได้รับการฝึกฝนมาแล้ว เปรียบเทียบกับผลของระดับกลูโคสจากเลือดที่เจาะในตำแหน่งเดียวกัน เลือดได้รับการปั่นและพลาสมาถูกเก็บส่งไปยังห้องปฏิบัติการเพื่อตรวจหาระดับกลูโคส

ผลการศึกษา : จากการวิเคราะห์พบว่าค่าที่ได้จากเครื่องอ่านระดับน้ำตาลที่มีจำหน่ายชนิดหนึ่ง® และห้องปฏิบัติการมีความสัมพันธ์กันอย่างมีนัยสำคัญทางสถิติ ($r = 0.97$, $p < 0.001$) และได้ผลจากการวิเคราะห์ดังนี้ เครื่องอ่านระดับน้ำตาลที่มีจำหน่ายชนิดหนึ่ง® = กลูโคสจากห้องปฏิบัติการ – 0.17 ($n = 175$) และพบว่าความเข้มข้นของเลือด (hematocrit) มีผลกับค่าของน้ำตาลโดยความเข้มข้นที่สูงจะได้ค่าอ่านสูงกว่าความเป็นจริง (ความชันบวก 0.04) แต่อย่างไรก็ตามค่าดังกล่าวมีความหมายน้อยในทางคลินิก

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