THE USE OF A REFLECTANCE COLORIMETER, CALIBRATED WITH LOW RANGE STANDARDS, IN THE DIAGNOSIS OF HYPOGLYCAEMIA IN NEONATES

C.C. Toh
N.K. Ho

SYNOPSIS

The relationship between blood glucose estimations by the Beckman Glucose Analyser and estimations by Dextrostix with the EYETONE Colorimeter calibrated with recently available "Low-Range Standards", was determined. The two methods were compared in two ways: (a) with nurses carrying out tests using the EYETONE Colorimeter and Laboratory Technicians using the Beckman Glucose Analyser, on a total of 143 pairs of blood samples; and (b) with laboratory technicians carrying out both the Dextrostix/EYETONE tests and the Beckman Glucose Analyser tests on a total of 98 pairs of blood samples. There were good correlations between the Dextrostix/EYETONE results and the Beckman Glucose Analyser results in both study designs. The clinical relevance of the Reflectance Colorimeter in the management of Hypoglycaemia in Neonates is discussed.

INTRODUCTION

The use of a glucose-specific test strip as a screening test for hypoglycaemia has become fairly routine practice in many neonatal units managing newborn infants at risk to hypoglycaemia. Reflectance colorimeters, such as the **EYETONE** (Ames Company, Elkhart, Indians, USA) have been used to augment the accuracy of the glucose estimations. However, the **EYETONE** instrument requires standardisation with known glucose "standards" and these were initially available as a 130 mg/dl **"DEXTROCHEK STANDARD"** together with **"DEXTROCHEK - CONTROLS"** at 90 mg/dl and 250 mg/dl. Calibrated in such a manner, the **EYETONE** was found to be useful in the management of Diabetics with blood glucose in the high range (ie greater than 100 mg/dl.). The Ames Company has marketed **"LOW RANGE STANDARD & CONTROLS"** at 20 mg/dl and 40 mg/dl of nominal glucose values, with the aim of making **EYETONE** readings more accurate in low glucose range as found in hypoglycaemic infants.

The objective of this study is to determine the relationship between **EYETONE** estimations (calibrated with the new low-range controls) and conventional blood glucose measurements by the **BECKMAN GLUCOSE ANALYSER** (Beckman Instruments Inc., Fullerton, CA, USA).

Neonatal Department
Toa Payoh Hospital
Toa Payoh Rise
Singapore 1129

C.C. Toh, AM, MBBS, M Med (Paediatrics)
Senior Registrar

N.K. Ho, AM, MBBS, M Med (Paediatrics), FRACP
Senior Paediatrician &
Head of Department

MATERIAL AND METHOD

Plasma Glucose concentrations obtained by the two methods were compared in two ways:

(a) With a team of nine staff nurses doing the **EYETONE** tests and two senior laboratory technicians performing glucose analysis on the Beckman Glucose Analyser;

(b) With two senior laboratory technicians doing both the **EYETONE** tests and the Beckman Glucose Analyser tests.

In part (a), the **EYETONE** instrument was kept on 24 hours of the day in the nursery. Daily calibrations and control procedures, as recommended by the manufacturer, were strictly adhered to. Following heel prick, a large drop of blood was smeared on to a **"DEXTROSTIX"** test strip (Ames Company, Elkhart, Indiana, USA) and glucose estimation with the **EYETONE** colorimeter was carried out according to manufacturer's instructions (1). A second nurse continued to collect blood from the heel prick site into a fluoridated and oxalated tube (25 mcg of sodium fluoride & 75 mcg of potassium oxalate). This sample was sent to the laboratory for glucose determination by the Beckman Glucose Analyser, within 12 hours of blood collection. With fluoridation of the blood samples, the problem of glucose consumption by red cells was avoided. The results of the **EYETONE** tests were not known to the laboratory staff doing the glucose analyses. The same nine staff nurses were rostered throughout the study period to carry out the **EYETONE** tests. This arrangement was necessary because of staff constraints. A total of 143 pairs of glucose estimations were obtained in this way, from 143 samples of capillary blood.

In part (b) of the study, capillary blood samples were collected in oxalated tubings from heel pricks. A single sample collected from one patient at a time, was sent immediately to the laboratory where a large drop of blood was used immediately (by one of two senior laboratory technicians) to perform the Dextrostix test. The **EYETONE** colorimeter previously calibrated with Low-Range standards according to the manufacturer's instructions, was used to estimate the glucose value from the Dextrostix test strip. The **EYETONE** tests were always done before the Glucose Analyser tests. The remainder of the oxalated blood was spun in a microcentrifuge and the plasma glucose concentration was determined with the Beckman Glucose Analyser. This instrument was in routine laboratory use and was regularly calibrated and subjected to external inter-laboratory quality control. As the Glucose Analyser gives an end-point display of result, foreknowledge of the **EYETONE** result was unlikely to have influenced the performance of the Glucose Analysis. A total of 98 pairs of glucose determinations (**EYETONE & Beckman Analyser**) were obtained in this way from 98 samples of capillary blood. The same two senior laboratory technicians performed all the tests during this study.

RESULTS

There was good correlation between the glucose determinations by the two methods carried out in the two ways described in parts (a) and (b):

For part (a), ie incorporating "Nurses' data", the correlation coefficient, r was 0.81 ($p<0.001$) and the regression equation was: $Y = 8.82 + 0.66X$

For part (b), ie the "Technicians' data", the correlation coefficient was $r = 0.94$ ($p<0.001$) and the regression equation was: $Y = -11.08 + 0.97X$

The Scatter Diagrams in Figures 1 & 2 show the relationship between Dextrostix/EYETONE values and True Glucose values by the Beckman Glucose Analyser, for "Nurses data" and "Technicians data" respectively.

The marginally closer correlation achieved by the laboratory technicians indicates smaller inter-observer variation between the two technicians doing the tests, compared with the team of nine nurses.

DISCUSSION

In the clinical management of neonates at risk to hypoglycaemia, it is important to have a rapid screening test to detect the hypoglycaemic state (2). Glucose specific test strips such as **"DEXTROSTIX"** give semi-quantitative measurements and fulfil the role suitably (3). From the point of view of clinical intervention, it is not necessary to quantitate blood glucose values below 1 mmol/l (18 mg/dl) because all definitions of hypoglycaemia currently in use would accept 1.1 mmol/l (18 mg/dl) as hypoglycaemic (4, 5). In our unit, all patients with blood glucose of less than 1.66 mmol/l (30 mg/dl) are picked out for further observation and treatment (6). The question of correlation between actual glucose levels as determined by glucose analysis and glucose levels as determined by the **EYETONE** instrument is largely academic for values below 1.66 mmol/l (30 mg/dl) as knowledge of such values does not materially change the course of clinical management. Frantz and colleagues (3) and Schersten and associates (7), have demonstrated good correlation between **EYETONE** readings and True Glucose values over all ranges of blood glucose levels, using only the ordinary normal range **"CONTROLS & STANDARD"**.

The **DEXTROSTIX** test strip, read by the human eye in conjunction with the colour strip chart provided by the manufacturer, is able to discriminate greater than and lesser than 1.5 mmol/l (25 mg/dl), thus allowing a diagnosis of hypoglycaemia to be made easily. In comparison, the performance of the **EYETONE** tests requires the operator to attain a high level of proficiency in carrying out considerable numbers of steps of operation. Timing between steps is critical for accuracy in **EYETONE** measurements. For values below 2 mmol/l, a delay in the reading of the reacted strips causes a severe degree of error. (personal observation). The added degree of accuracy derived from the use of Low-range standards with the **EYETONE** colorimeter is therefore achieved only with increased care and workload. The benefit of such improved accuracy is at best academic. The pick up rate of hypoglycaemia is not appreciably improved in our unit since the **EYETONE** instrument was used in this study. (personal unpublished data) Formal glucose analysis is still required to document the occurrence of hypoglycaemia. In borderline cases, glucose

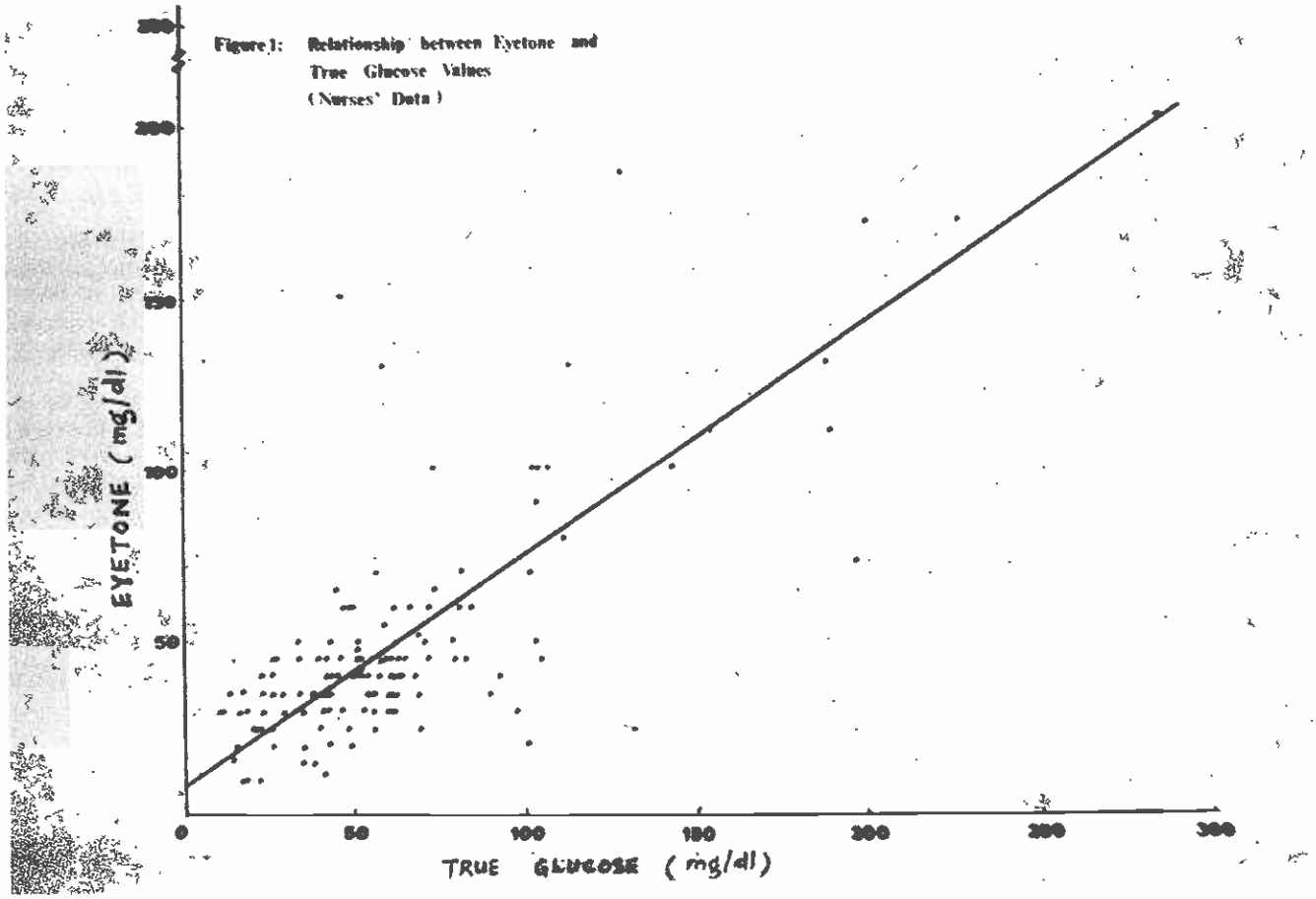

Figure 1

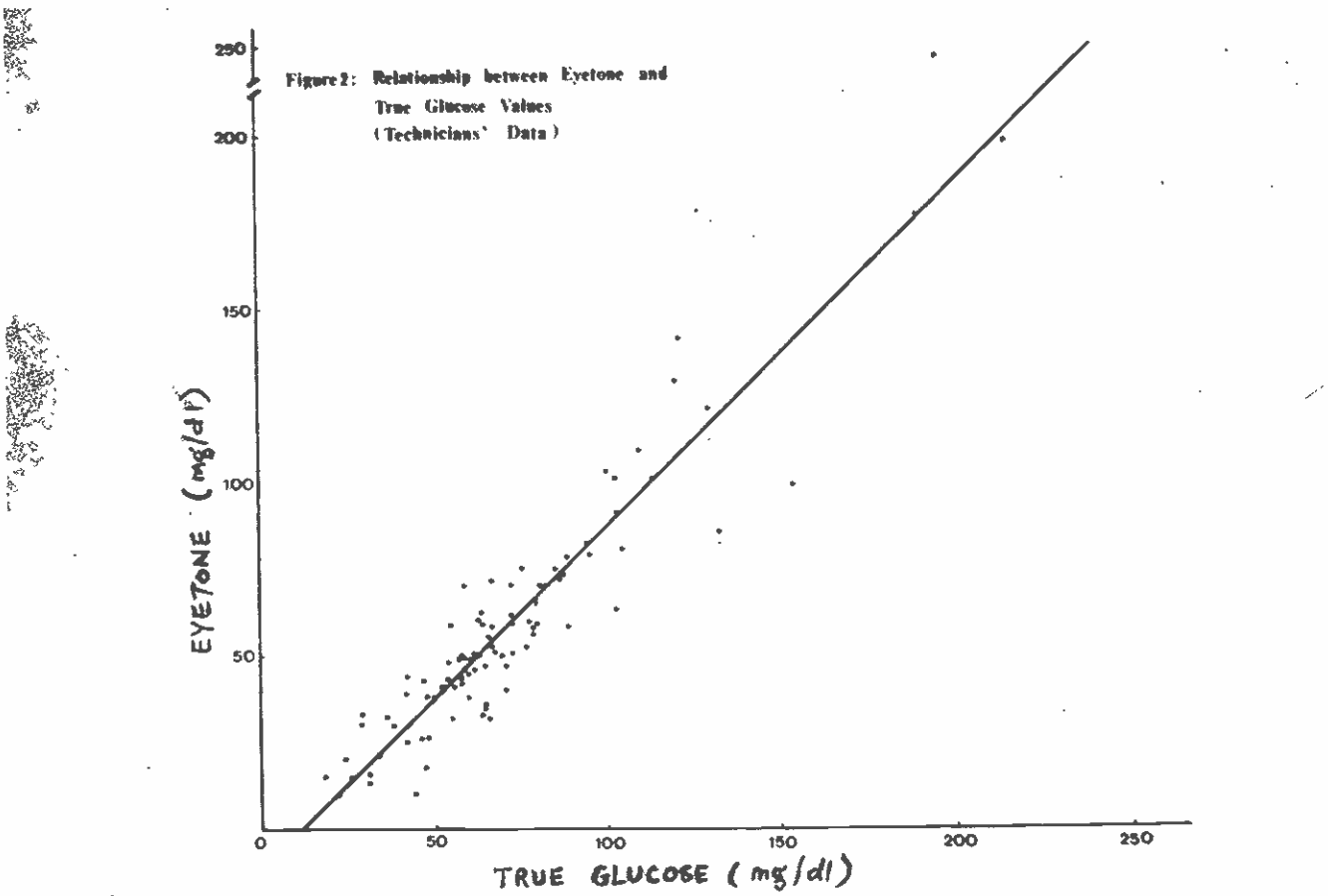

Figure 2

determinations by conventional glucose analysers, is vital to the decision of whether a patient shall receive parenteral glucose therapy.

Our final conclusion is that the Glucose specific test strip is suitable as a screening test and should be the mainstay of any screening protocol for hypoglycaemia. It is doubtful if a reflectance colorimeter is useful for detection and management of hypoglycaemia in Neonates.

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