

QUALITY ASSESSMENT OF GLUCOSE ESTIMATION BY REFLOCHECK GLUCOSE METER AT NURSING STATIONS. AN EXERCISE IN EXTRA LABORATORY TESTS

Pages with reference to book, From 75 To 78

Mirza Naqi Zafar (Department of Pathology, The Aga Khan University Hospital, Karachi.)
Rukhsana Lalani, Mohammed Khursheed (Department of Pathology, The Aga Khan University Hospital, Karachi.)
Rubina Kazmi (Department of Medicine, The Aga Khan University Hospital, Karachi.)

Abstract

The use of reagent strips to monitor blood glucose concentrations via glucose meters in diabetic patients is gaining popularity mainly due to their favourable performance as compared to the autoanalyser methods. As part of a programme of extra laboratory tests, such estimations were performed at a medical nursing station and results compared with simultaneous estimations in the clinical laboratory on autoanalyser. Observations in the first three months of the trial by untrained and unspecified operators were % total difference 16.0 ± 18.6 . The % of results more than and less than autoanalyser were 13.2 ± 16.2 and 18.7 ± 21.4 respectively. During the second three months of the trial results were returned by one specified and trained operator. Results as compared to the autoanalyser were, % total difference 10.09 ± 12.4 , more than 8.78 ± 10.9 and less than 14.0 ± 16.0 . In this second trial the % total difference in glucose range 100—200 mg/dl was 8.25 ± 6.47 , in range 200-300 mg/dl was 9.9 ± 15.0 and range 300-400 mg/dl was 13.9 ± 16.3 . The results of the second trial conducted by a single trained operator were better than the first trial because majority of the results were within or around 10% accepted deviation. Results show the use of reagent strips and Reflocheck at nursing stations are a viable proposition for monitoring diabetic patients, provided the tests are conducted by trained and specified operators. Our results also confirm observations that results obtained by strip glucose meters are comparable to standardised laboratory estimation of glucose. We conclude that strict quality control is necessary for the use of these strips in the hospital, clinic and home environments (JPMA 38: 75 , 1988).

INTRODUCTION

The analyses on patients specimens are traditionally performed by laboratory personnel within their own laboratories. With the development of disposable dry chemistry systems e.g., urine strips, dextro Stix and portable analysers e.g., glucometers, Reflocheck haemoglobinometers, many simple tests are increasingly being performed by non-laboratory staff in wards and clinics. Anticipating such trends, a programme of extra laboratory tests was initiated at The Aga Khan Hospital and Medical College. This programme was conducted adhering to the recommendations of Association of Clinical Pathologists¹ for extra laboratory tests. The use of reagent strips in glucose meters to monitor blood glucose concentrations in diabetic patients is gaining popularity mainly due to their favourable performance compared to standardised autoanalyser methods² after allowance of differences in chemistry systems and between capillary and venous blood. Their use from self monitoring by diabetics in home environment has extended to clinics and wards³. To initiate our programme of extra laboratory tests, we started glucose estimations of finger prick capillary blood samples of known diabetic patients at a medical nursing station, by non-laboratory staff using a dry strip glucose meter . Simultaneous venous blood samples were sent to the clinical laboratory for glucose estimation by autoanalyser. We report our

approach in setting up this extra laboratory procedure and the performance of the glucose meter in terms of usability by nonlaboratory staff and the reliability and accuracy of results obtained as compared to standardised autoanalyser results of the clinical laboratory.

MATERIALS AND METHODS

A Reflocheck Glucose meter (Boehringer) was installed at a medical nursing station with reagent strips, disposable lancets and finger pricking device. Instructions on the use of the glucometer, given to resident medical officers and nurses, were: 1. Switch on the Reflocheck by pressing the orange ON/OFF button, 2. apply the blood sample (second drop) to the test patch (do not spread or smear the drop), and 3. then immediately press yellow start button. 4. After 1 minute (when the buzzer sounds and the display starts flashing) wipe off the blood, 5. smoothly and steadily insert the strip with the test patch facing upwards, 6. result is displayed automatically, 7. press white button and then withdraw the strip. The users were requested that each time a glucose estimation is done, a simultaneous venous blood sample should be sent to the laboratory in the yellow fluorinated tubes provided. They were also requested to fill in a performance form (Table I)

TABLE I
Format of the Performance form.

Name	No of Pricks for Blood	Time Test done	Result mg/dl
Instrument	Instrument	Cause of T.S.	
Operational	Trouble Shooting	Please State	
Status	Yes/No	Briefly	
OK/NO	Please Tick		
Please Tick			
Date	USER		

each time a test was done and send their results with this form and the venous blood sample. The workability of the glucose meter was checked periodically by the lab staff and the accuracy of the instrument controlled by calibrated reagent strips with known glucose concentrations 100 and 300 mg/dl. Glucose estimations in the clinical laboratory were performed on a BECKMAN ASTRA autoanalyser using glucose—oxidase peroxidase technique. These results were controlled internally by commercial control sera and externally by Well-come and MEQAS quality control schemes. During the three months of this trial, 41 results were sent to the clinical lab along with performance forms and blood samples. The results and workability of the glucose meter were discussed with the medical staff. In view of the findings a decision was taken to continue the trial for another three months. This second trial, however, was to be conducted by one trained and specified resident medical officer. During this trial 47 results were returned along with performance forms and blood samples. Retrospectively first three months were called the First Trial and the second three months Second Trial.

RESULTS

Comparison of the Reflocheck and autoanalyser estimations of glucose in the first trial show wide variations in the two systems as graphically represented in Figure 1.

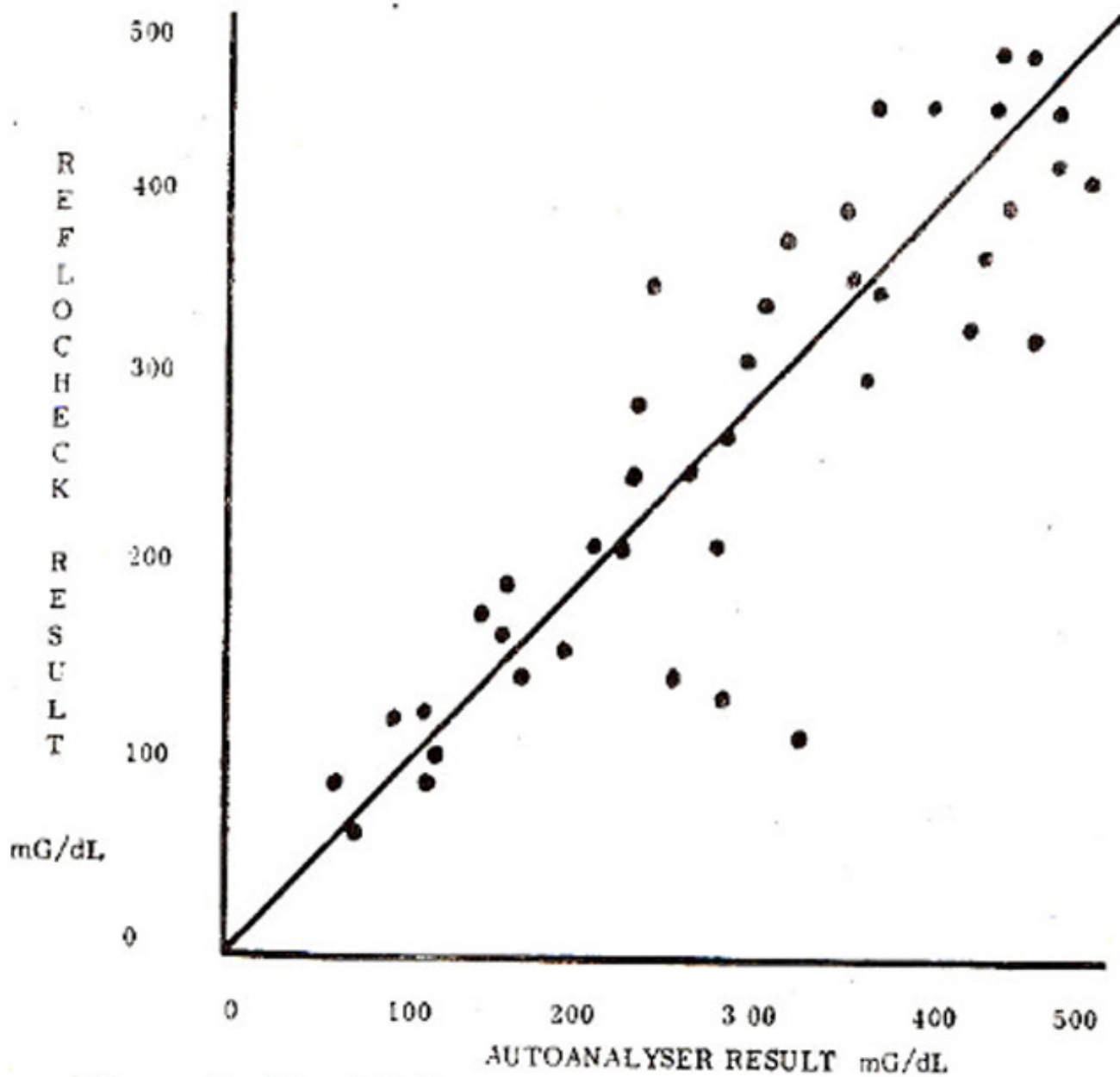


Figure 1. First Trial.

The % of difference of glucose values in mg/dl of the two methods are given in

TABLE II
Comparison of Reflocheck and Autoanalyser
Results in the First Trial.

Deviation from Autoanalyser	% OF mG/dL difference
Overall	16.0 ± 18.6
More Than	13.2 ± 16.2
Less Than	18.7 ± 21.4

Table II and the results are markedly deviant from the manufacturers' recommended 10% deviation. This 10% deviation is expected and accepted partly due to the differences in chemistry system of the two methods and partly due to the difference in glucose levels in capillary and venous blood, since they tend to be about 10% higher in the capillary blood. Analysis of data from the performance forms is given in Table III.

TABLE III
Analysis of performance form data in the First Trial.

Success in getting Sample in one Prick	95%
Instrument Operational Status	OK 95%
Trouble Shooting	YES 27%
Cause of Trouble Shooting	
Unable to read Strip (Improper Insertion)	100%

This shows that the instrument was operational most of the time and most users were able to use it correctly, the main reason for occasionally not getting the results being improper insertion. During this trial 41 results were received by the clinical lab with performance slips and blood samples. The results of the first trial were unacceptable since they were markedly deviant from the accepted 10% limits. Operator error was seriously considered and one trained operator was asked to conduct the second trial. Comparison of Reflocheck and autoanalyser results show better correlation as graphically represented in Figure 2.

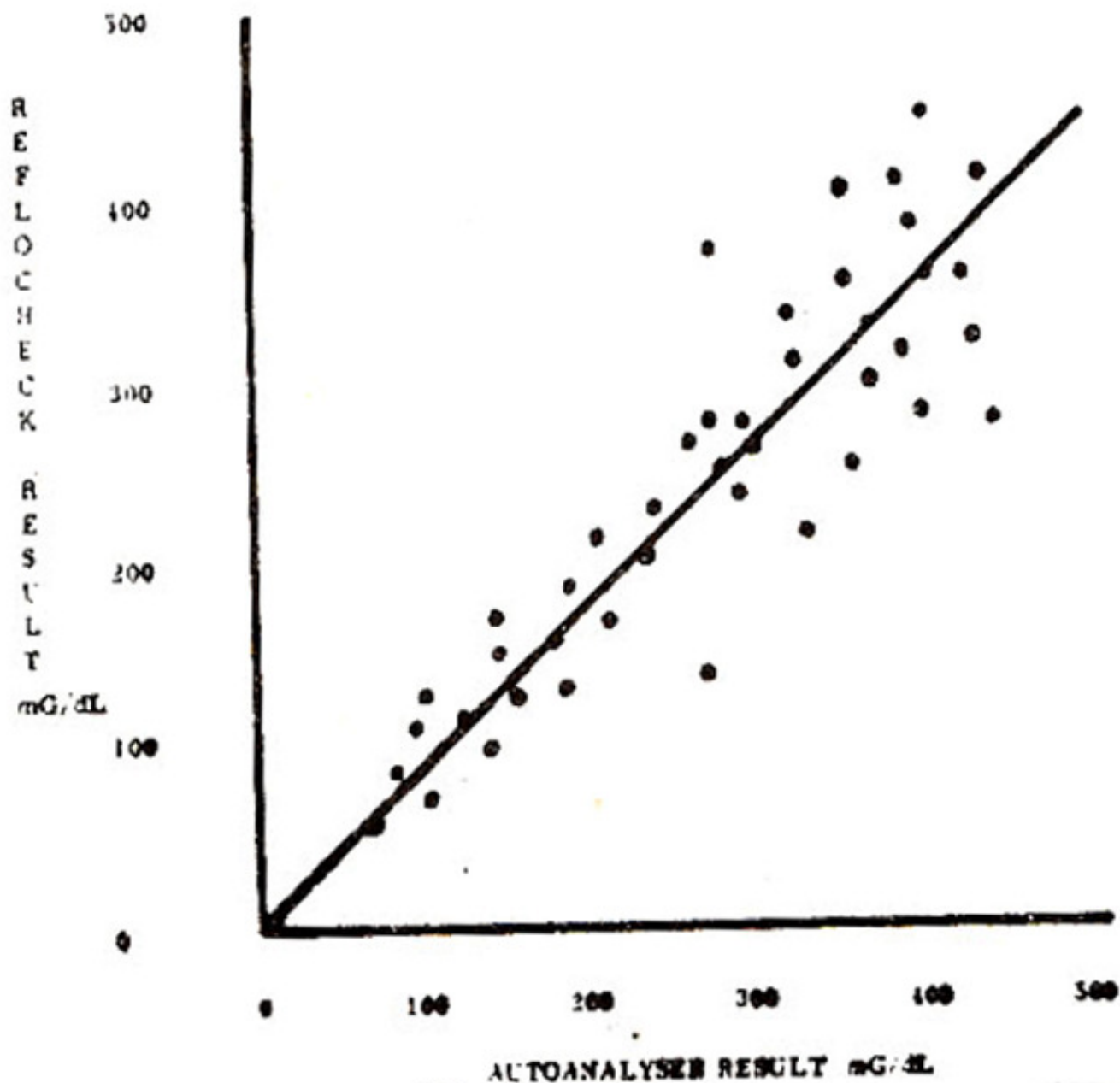


Figure 2. Second Trial.

The % of difference in glucose values in mg/cl are given in Table IV

TABLE IV
Comparison of Reflocheck and Autoanalyser Results
in the Second Trial.

Deviation from Autoanalyser	% OF m/G/dL difference
Overall	10.09 $\pm$ 12.4
More than	8.78 $\pm$ 10.9
Less than	14.0 $\pm$ 16.0

which shows that most results are within 10% deviation. Total deviation % in various glucose ranges is within accepted 10% except 300-400 range (Table V).

TABLE V
Comparison of Reflocheck and Autoanalyser Results
in various Glucose ranges in Second Trial.

Glucose Range mG/dL	% Overall Deviation in mG/dL
100 – 200	8.25 $\pm$ 6.47
200 – 300	9.9 $\pm$ 15.0
300 – 400	13.9 $\pm$ 16.3

Analysis of data from performance slips shows excellent efficiency both by user and instrument (Table VI).

TABLE VI
Analysis of Performance Data in the Second Trial.

Success in getting Sample in One Prick	98%
Instrument Operational Status	OK 98%
Trouble shooting	YES 05%
Cause of Trouble Shooting	
unable to read Strip(Improper Insertion)	100%

The second trial shows marked improvement in results (Tables II and IV).

DISCUSSION

The advent of solid state dry chemistry reagent strips and portable analysers have increased the possibilities and accuracy of extra-lab tests. Acceptable results initially obtained with these systems in the home and clinic environments have extended their use to hospital wards. From single estimation systems, e.g., glucose and haemoglobin, portable analysers are now able to perform most routine chemistries with single or multiple reagent strips⁴. Our Medical department was keen to undertake performance of simple tests at nursing stations. Therefore the clinical laboratory started its programme of extra laboratory tests. Blood glucose measurement was an estimation of choice due to ready availability of glucose meters and their known accuracy.⁵ The first trial, un-controlled as far as the selection of users were concerned, returned poor results markedly deviant from the 10% accepted limits, mainly due to the inability to use the glucometer correctly. Too high results (16.0 ± 18.6 % Table II) were attributed to delayed insertion of the strip, since time fraction can adversely effect the results with such strips⁶. And the accepted 10% high glucose expected in capillary blood samples.⁷ Too low results (18.7 ± 21.4 % Table II) were attributed to smearing or spreading of a small drop of blood to the surface area of reaction. These results formed the basis of the decision to identify one trained user to conduct the second trial. Consequently, the results improved remarkably in this trial with overall deviation of around 10%. This gave the clinical laboratory and the medical staff confidence to initiate glucose meter blood glucose estimations at nursing stations, our first extra laboratory test. A few well trained operators were requested to use the Reflocheck. The Reflocheck has not replaced the standard glucose estimation in the laboratory, all inordinately high or low results are always confirmed in the clinical lab. Furthermore problem diabetics are usually monitored by the clinical lab. We conclude that Glucose estimation by glucose meters at nursing stations in our set up is a viable proposition, provided strict quality check is maintained on who uses the instrument and that the laboratory controls the workability and accuracy of the instrument - Our results further confirm other's observations that glucose meter results are comparable to standardised laboratory estimations, after allowance of differences in chemistry reagent of the two systems and the difference of glucose level in capillary and venous blood. Finally since the conclusion of this trial the Reflocheck has been in use for several months and we have encountered no problems.

ACKNOWLEDGEMENT

We are grateful to S. Ejazuddin and Company for providing the Reflocheck reagent strips and lancets and (Boehringer) for making this study possible.

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