

Primary Health Care Department of Family Medicine Department
Medical University of Lublin

TERESA NICER, GRAŻYNA MARDAROWICZ, JERZY ŁOPATYŃSKI

*Usefulness of glucose levels determination with glucometer
in epidemiological research*

Diagnosis of diabetes according to the presently recommended criteria is based on the blood glucose level measurement: fasting, after 75 g glucose load or in casual tests. Over the last couple of decades the criteria for recognition have changed many times. Nowadays the WHO criteria dating from 1985 are used most frequently (9) though ADA criteria are used pararely (2) and the WHO recommendations presented by Zimmet and Alberti are coming into life (1). The value of glicaemia is the only one stated in the diabetes recognition criteria (though these values differ from each other according as they are measured in the capillary, whole blood, vein blood or in serum). The method which should be used for determining the glucose concentration level is not precisely defined. Starting the research project *Primary and Secondary Prevention and Its Influence on Epidemiologic and Economic Factors in Type 1 and Type 2 Diabetes in the Polish Population* carried out also in the Krakow and Lodz centers (Prof. Zbigniew Szybiński was the project leader) we faced the problem of determining glicaemic levels of patients from rural health centers. Transport of whole blood samples from rural health centers frequently lasts for many hours and takes place in extreme temperatures (summer, winter; despite the thermal shields used) – it does not let us control the speed of glicolysis and thus leads to false results. In order to avoid this problem we decided to measure the glucose level by means of a glucometer. As there is traditional distrust towards the results obtained in this way, we checked the reliability of glucose levels measurements performed with a modern glucometer. Over the years not only glucometers have been improved, but also glucose levels determination methods. At the end of the 1980s the glucose level was tested by means of Hultman's ortho-toluidine method where all components with reducing properties are marked. Presently almost all laboratories selectively use the enzymatic method with glucose oxidase (4).

SUBJECTS AND METHODS

131 patients successively reporting to a diabetologic outpatient clinic were examined. They were recommended by their managing doctors to have blood samples taken in order to carry out laboratory tests (91 women and 40 men). Fasting vein blood samples were taken from each patient into a probe with a preservative NaF (sodium fluoride) in order to determine glucose concentration level in serum in a laboratory. Then a drop of the blood was put on a glucometer strip to measure the glucose concentration level. Immediately after this a fingertip was pricked and

the capillary blood obtained in this way was used to make the glucose concentration level measurement with a glucometer.

The laboratory test was performed on the semiautomatic analyser Cobas DP-25 by means of the enzymatic method using the diagnostic test produced by Cormay. Glucose concentration levels were measured with the Glucotrend glucometer by Roche. The operating principle of this appliance is based on an optical system, which emits red light going through the measurement areas where a drop of blood has been applied. The change in colour of the measurement areas is caused by the reaction catalyzed by glucose oxidase. The measurement of the color change is automatic and involves reflectophotometry. The method is based on the comparison of luminance (brightness) of the examined surface with a white and matt surfaces treated as a reference pattern and the photometric reading. The capillary blood test was performed with a glucometer in an identical manner as the whole vein blood test and according to the manufacturer's instructions (7).

RESULTS

Mean glucose concentration levels were compared in particular schemes- (t-Student's test for interdependent variables). Data are presented in Figures 1–3. Pearson's correlation index and the equation of regression line were used as a measure of correlation. The correlation index for glucose concentration levels amounted to: glucose in drops of capillary blood and drops of vein blood by means of glucometer- $r=0.9768$; glucose in drops of capillary blood measured with the Glucotrend glucometer and glucose in vein blood serum by means of the laboratory method- $r=0.9749$; glucose in drops of vein blood measured with the Glucotrend glucometer and glucose in vein blood serum by means of the laboratory method- $r=0.9772$. Precise data regarding the correlation are presented in Figures 1–3. Regression analysis allows to determine the statistical correlation between the concentration level of vein blood glucose (Y) and serum glucose (X). The equation of the regression line for the scheme of glucose concentration levels in drops of capillary blood measured with the glucometer and vein blood glucose measured with the glucometer (Glucotrend) has the following form: $y=6,86+(0,97 * x)$. The equation of the regression line for the scheme of glucose concentration levels in drops of capillary blood measured with the Glucotrend glucometer and vein blood serum glucose measured with the laboratory method has the following form: $Y=-14,76+(0,97 * X)$. The equation of the regression line for the scheme of glucose concentration levels in vein blood drops measured with the Glucotrend glucometer and vein blood serum glucose measured with the laboratory method has the following form: $Y=-12,05+(0,98 * X)$. A statistically significant correlation ($p<0,05$) was found in all the analysed cases.

Table 1. Comparison of mean glucose concentration levels obtained with glucometer in capillary blood and vein blood (t-Student test for dependent variables)

Material	Average	SD	T	p
Capillary blood	145,98	56,89	2,36	< 0,05
Vein blood	143,44	57,29		

Mean glucose concentration in capillary blood is statistically significantly higher ($p < 0,05$) than mean vein blood glucose concentration level

Table 2. Comparison of mean glucose concentration levels obtained with glucometer in capillary blood with mean blood serum glucose concentration levels obtained with the laboratory method (t-Student test for dependent variables)

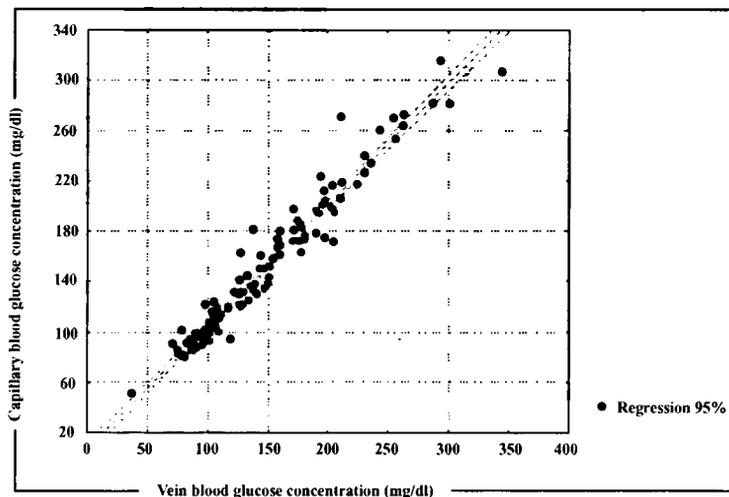
Material	Average	SD	T	p
Capillary blood	145,98	56,89	-3,59	< 0,001
Serum / laboratory method	150,72	63,70		

Mean glucose concentration in capillary blood is statistically significantly higher ($p < 0,05$) than mean serum glucose

Table 3. Comparison of mean vein blood glucose concentration level results obtained with a glucometer with mean serum glucose levels measured with the laboratory method (t-Student test for dependent variables)

Material	Average	SD	T	p
Vein blood	143,44	57,29	-5,78	< 0,001
Serum / laboratory method	150,72	63,70		

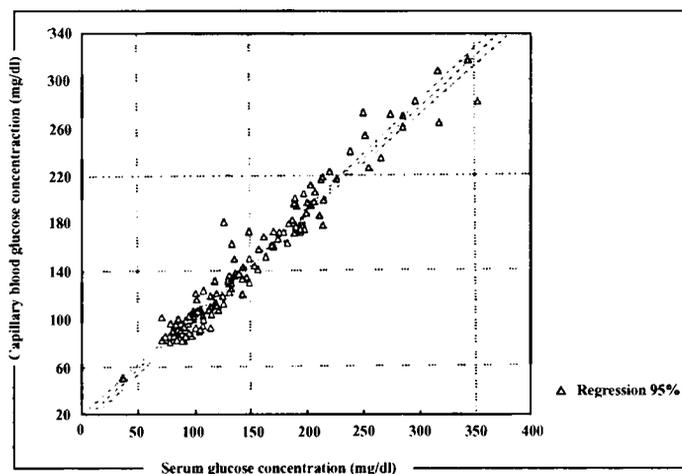
Mean vein blood glucose concentration level is statistically significantly lower ($p < 0,05$) than mean serum glucose concentration level



Regression analysis allows to determine the statistical correlation between capillary blood (y) and serum (x) glucose concentration levels

$$y = -14.76 + (0.97 * x)$$

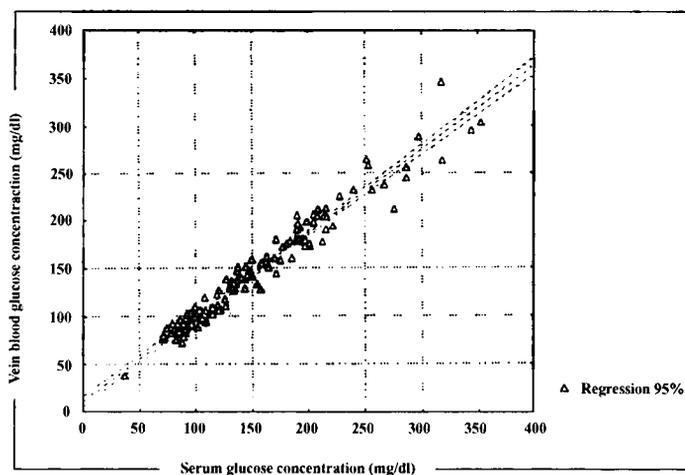
Fig. 1. Analysis of regression and correlation of capillary and full vein blood glucose concentration results. Roche's Glucotrend glucometer. Correlation ratio $r=0.9768$ ($p < 0.05$); determination ratio $r^2=0.9541$



Regression analysis allows to determine a statistical correlation between capillary blood (y) and serum (x) glucose concentration level

$$y = -14.76 + (0.97 * x)$$

Fig. 2. Analysis of regression and correlation of capillary blood (Roche's Glucotrend glucometer) and vein blood serum (laboratory method) glucose level tests. Correlation ratio $r=0,9749$ ($p<0,05$); determination ratio $r^2=0,9504$



Regression analysis allows to determine the statistical correlation between vein blood (y) and serum (x) glucose concentration levels

$$y = -12.05 + (0.98 * x)$$

Fig. 3. Analysis of regression and correlation of whole vein blood (Roche's Glucotrend glucometer) and vein blood serum (laboratory method) glucose level tests. Correlation ratio $r=0.9772$ ($p<0.05$); determination ratio $r^2=0.955$

SUGGESTIONS

Precision and repeatability of the results of glucose concentration levels measurements by means of the modern glucometer as well as some reservations to the quality of the laboratory tests results make it possible to use the glucometer as a tool for diabetes recognition in epidemiological studies.

DISCUSSION

Many practitioners still adhere to the view that the diabetes recognition by means of test strips requires a confirmation with laboratory methods. We believe, however, that this standpoint should be revised for at least three reasons: firstly, the modern glucometers have reached a very high level of precision and the repeatability of the test results is quite satisfactory (8); secondly – and this we proved in this paper, there is a very good correlation and statistically high significant correlation between glucose concentration levels measured with the glucometer and laboratory methods; thirdly, there are some doubts regarding the diagnostic value of laboratory glucose concentration levels tests. A possibility of an error appears already on the stage of the blood storage after its samples are taken. It is known that the blood glucose level decreases by about 5% per hour from the moment the sample is taken, which also depends on the environment temperature. Moreover, in the National Laboratory Verification carried out in 1998, almost 40% of the obtained results of glucose concentration levels were doubtful or unsatisfactory as compared to the nominal values declared by the producers of control materials (3,5). The following years saw an improvement but as the quality of laboratory tests is still low, it is hard to agree with the statement that these are laboratory tests which are to confirm the diagnosis based on glucometer strip tests. The conditions specific to Polish laboratories should also be taken into account. After the reform was implemented, the economic criterion became one of the most considered ones. This cause the liquidation of a part of laboratories and the necessity of transporting the test material to other labs. What is more, a lot of small private laboratories appeared which offer cheap tests at the cost of their quality (6). The above mentioned conditions that form the „wild laboratory market” in Poland cause that there is no satisfactory guarantee that the laboratory results are better than the ones obtained by means of a modern glucometer.

Apart from our conviction about the usefulness of the glucometer in epidemiological studies, we also believe that recognition of diabetes by means of the glucometer (double confirmation with the glucometer) should also be accepted as a method applied by a general practitioner. Determination of glucose concentration by means of a glucometer and laboratory methods, if certain criteria are used (glucose concentration level in plasma is by 10-15% higher than in whole blood), are equally useful. Technological progress in laboratory tests made them anonymous. A doctor usually does not know with whom he works. He needs a guarantee that the laboratory is reliable and such guarantee he frequently does not have. In this situation, a precise glucometer can give this guarantee if the measurement procedure is fully complied with.

After the reform was implemented, the economic criterion became the most important one- laboratories started to be liquidated. This liquidation is connected with the necessity of transporting of test samples which, among others, influences the error margin of results. It is known that the blood glucose level decreases by 5% within an hour from the moment it was taken. In the National Laboratory Verification carried out in 1998, almost 40% of the obtained results of glucose concentration levels were doubtful or unsatisfactory as compared to the nominal values declared by the producers of control materials. The following years saw an improvement but as the quality of laboratory tests is still low, it is hard to agree with the statement that these are laboratory tests which are to confirm the diagnosis.

REFERENCES

1. Alberti K.G.M.M., Limmert P.Z.: Definition, Diagnosis and classification of Diabetes Mellitus and its Complications Report of a WHO Consultation Part 1: Diagnosis and Classification of Diabetes Mellitus. WHO, Geneva. 1999.
2. American Diabetes Association: Screening for type 2 diabetes. *Diabetes Care*, 1999,22,20-23.
3. Brzeziński A., Przybył-Hac B.: Powszechny program sprawdzianów międzylaboratoryjnych w Polsce w roku 1998. *Diagn. Lab.*, 35, 33-49, 1999.
4. Brzeziński A., Jasińska A., Przybył-Hac B.: Ocena zmian w diagnostyce laboratoryjnej w Polsce. III Dostępność badań i wykorzystywane metody. *Diagn. Lab.*, 32, 421, 1996.
5. Brzeziński A., Przybył-Hac B.: Ocena poprawności wyników oznaczeń laboratoryjnych w Polsce na podstawie przeprowadzonych w 1999 r. sprawdzianów międzylaboratoryjnych. *Diagn. Lab.*; 36, 7-24, 2000.
6. Dziki rynek laboratoryjny, wywiad z prof. Jerzym Naskalskim. *Gazeta Lekarska*, 1, 34, 2001.
7. Glucotrend firmy Roche - instrukcja obsługi.
8. Glucotrend Plus Glucose, Documents for Registration, Version: 26.10.99.
9. World Health Organisation: Diabetes Mellitus: Report of WHO Study Group, Geneva, Technical Report Series, 727, 1985.

SUMMARY

A decentralised health care system based on family doctors implies a certain return to a traditional model, that is to the performance of simple diagnostic tests by the doctor himself.

This tendency is getting stronger. In such situation, the approach towards the results obtained with the glucometer should be revised. Carrying out our comparative study on determining 131 patients' glucose concentration levels in capillary blood, whole vein blood (Roche's Glucotrend glucometer), and vein blood serum by means of the laboratory method (the Cobas DP 25 semi automatic method, glucose concentration level tests produced by Cormay) we come to the conclusion that these tests are equally useful.

Użyteczność pomiarów poziomu glukozy za pomocą glukometru
w badaniach epidemiologicznych

Zdecentralizowany system opieki medycznej w postaci lekarzy rodzinnych implikuje pewien powrót do modelu tradycyjnego, czyli przeprowadzania prostych badań diagnostycznych przez samego lekarza. Tendencja ta nasila się. W tej sytuacji należy zrewidować swoje stanowisko co do wyników otrzymanych przy pomocy glukometru. Przeprowadzając badania porównawcze u 131 pacjentów przy oznaczaniu glukozy we krwi włośniczkowej, w pełnej krwi żyłnej (glukometr Glucotrend firmy Roche) w surowicy krwi żyłnej metodą laboratoryjną (metoda półautomatyczna Cobas DP 25, zestawy do oznaczenia glukozy firmy Cormay) dochodzimy do wniosku, że badania te są jednakowo przydatne.