

Glucocard X-Meter

Summary of an evaluation under the direction of SKUP Report SKUP/2006/50



Background

The Glucocard X-Meter blood glucose meter and the Glucocard X-Sensor test strips are designed for glucose self-measurements by diabetics. The meter and the test strips are produced by Arkray, Inc. and are supplied in Scandinavia by Tamro MedLab. Glucocard X-Meter and Glucocard X-Sensor have not yet been launched onto the Norwegian market.

In order to give reimbursement for the test strips, The National Social Insurance Office (*Rikstrygdeverket*) in Norway instructs the companies to carry out an evaluation that includes a user-evaluation among diabetics. The evaluation of Glucocard X-Meter/Glucocard X-Sensor is done under the direction of SKUP from October 2005 to January 2006. In the report Glucocard X-Meter/Glucocard X-Sensor will be referred to as Glucocard X-Meter.

The aim of the evaluation

The aim of the evaluation of Glucocard X-Meter is to

- reflect the analytical quality under standardised and optimal conditions (performed by biomedical laboratory scientists)
- reflect the analytical quality by the users (83 diabetics)
- compare the analytical quality among diabetics with and without training
- compare the analytical quality among diabetics before and after three weeks of practise
- check the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate Glucocard X-Meter regarding user-friendliness
- evaluate the Glucocard X-Meter user-manual

Materials and methods

83 diabetics took part in the evaluation. 40 participants had two consultations (the “training group”) and the rest had one consultation (the “post group”). At the first consultation the diabetics in the “training group” were given a standardised instruction about the Glucocard X-Meter before they did a finger prick and performed two measurements at the meter. The biomedical laboratory scientist also took capillary samples of the diabetics and measured twice at Glucocard X-Meter. In addition, two capillary samples were taken to a designated comparison method. The diabetics in the “post group” received the Glucocard X-Meter by post and no training was given. Both groups of diabetics carried out a practice period of approximately three weeks at home, before they were called for a final consultation. The blood glucose sampling and measurement procedures at the first consultation were repeated, and in addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants finally answered questionnaires about the user-friendliness and the user-manual of Glucocard X-Meter.

Results

- Glucocard X-Meter shows acceptable precision. The CV is approximately 5 % under standardised and optimal measuring conditions and slightly poorer when the measurements are performed by the diabetics with a CV of approximately 6 %.

- The trueness of Glucocard X-Meter is good. For glucose values > 10 mmol/L there is a significant bias between Glucocard X-Meter and the comparison method. Glucocard X-Meter gives glucose values approximately 0,6 mmol/L lower than the comparison method at this glucose level.
- The agreement with a designated comparison method is good. The quality goal set in ISO 15197 is achieved under standardised and optimal measuring conditions. When handled by the diabetics the results are within the “adjusted ISO-goal”.
- Two of the three lots of test strips that were used showed significantly lower values than the comparison method. The results still attain the quality goal.
- Glucose measurements at Glucocard X-Meter seem to be affected by hematocrit values. Glucose concentration > 10 mmol/L are affected by hematocrit in a higher degree than samples with glucose concentration < 10 mmol/L, but the tendency is the same. High glucose values in combination with high hematocrit values give an under-estimated glucose result, while high glucose values in combination with low hematocrit values are over-estimated. Hematocrit outside the range 32 – 51 % has not been tested.
- The diabetics summarise the Glucocard X-Meter device as easy to use. Most of them were pleased with the device. The diabetics that had used the user manual were satisfied with the manual.

Conclusion

Glucose measurements at Glucocard X-Meter have acceptable precision. The results obtained under standardised and optimal measuring conditions are within the quality goal set in the ISO-guide 15197. The measurements performed by the diabetics are within the “adjusted ISO-goal”. Two of the three lots of test strips that were used showed significantly lower values than the comparison method. The results still attain the quality goal. The glucose results seem to be affected by hematocrit. High glucose values in combination with high hematocrit values give an under-estimated glucose result, while high glucose values in combination with low hematocrit values are over-estimated. The users find the Glucocard X-Meter device easy to use and they are quite satisfied with the device.

Comments from Tamro MedLab

An information letter from Tamro MedLab is found in attachment 13 in the report.

The complete report is found at www.skup.nu