Ascensia Contour Glucose

Summary of the evaluation SKUP/2004/30

Background
Acsensia Contour is a meter designed for glucose self-measurements by diabetic patients. The meter is produced by Bayer HealthCare and is supplied in Scandinavia by Bayer. Ascensia Contour was launched onto the Norwegian market in the autumn of 2003.
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 diabetic patients. The evaluation of Ascensia Contour is done under the direction of SKUP during the spring of 2004.

The aim of the evaluation
The aim of the evaluation of Ascensia Contour is to

- reflect the analytical quality under standardised and optimal conditions (performed by two biomedical laboratory scientists)
- reflect the analytical quality by the users (app. 75 diabetics)
- compare the analytical quality before and after training and practice
- examine if hematocrit interferes with the measurements
- check the lot-variation of test strips
- evaluate Ascensia Contour regarding user-friendliness
- evaluate the Ascensia Contour user manual

Materials and methods
76 diabetic patients took part in the evaluation. All participants met twice at NOKLUS. At the first consultation the patients did a finger prick and performed two measurements on the Ascensia Contour meter, without further instructions. The biomedical laboratory scientist also took capillary samples of the diabetic patients and measured twice at Ascensia Contour. In addition, two capillary samples were taken to a designated comparison method. Then the diabetics were given a standardised instruction about the Ascensia Contour meter. In a practice period of approximately three weeks the diabetics used the meters at home, before they were called for a second 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 of the meter and about the user manual.

Results

- Ascensia Contour shows acceptable precision. The CV is < 5 % under standardised and optimal measuring conditions and approximately 5 % when the measurements are performed by diabetic patients.
- The agreement with a designated comparison method is good on certain conditions. Quality goals set in ISO 15197 and by ADA are achieved under standardised and optimal measuring conditions when using the first measurement of paired results. The second measurement in the pair is systematic higher than the first. When handled by the diabetic patients, Ascensia Contour shows good results initially. After three weeks of use at home the results are not as good as the initial ones. 80 % of these results are within the quality goals set in ISO 15197 and 90 % are within the “adjusted ISO-goal”. It is not clear why these results do not meet the quality goals.
- The three lots of test strips that were used showed no clinical significant bias from the comparison method.

- Glucose measurements on Ascensia Contour seem to be affected by the hematocrit values of the samples in a higher degree than described in the package insert. The glucose values are over-estimated when hematocrit is low and under-estimated when hematocrit is high. The hematocrit effect applies not only for high glucose values in combination with high hematocrit values, but is also true for glucose values below 11,1 mmol/L and for hematocrit values within the reference range. Although the glucose results under standardised and optimal conditions seem to be affected by the hematocrit, they were within ±15 % of the comparison method, as shown in figure 7.
- The diabetic patients summarise the Ascensia Contour device as easy to use. As a whole they were pleased with the device. The patients that had used the user manual were satisfied with the manual.

Conclusion

Glucose measurements on Ascensia Contour have acceptable precision. The results obtained under optimal measuring conditions are within the strict quality goals set by ADA. The measurements performed by the diabetic patients when the device is new are within the quality goals set in the ISO-guide 15197. After having been used at home and outside controlled conditions for three weeks, the device no longer performed satisfactorily. The results obtained after the practice period do no longer fulfil the quality goals. It has not been possible to find an explanation for this, but there is no reason to believe that the poor results are caused by user errors. The glucose results in this evaluation are affected by hematocrit in a higher degree than described in the package insert. The users say that the Ascensia Contour device is easy to use and they are quite satisfied with the device.

Comments from Bayer Diagnostics

A rebuttal to SKUP from Bayer HealthCare Self Testing Systems Division is found in attachment 12 in the report. An answer from SKUP is given in attachment 13.

The complete report is found at www.skup.nu