Ascensia Contour Glucose

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Summary of an evaluation organised by SKUP Report 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 glucose test strips in Norway, The National Social Insurance Office instructs the companies to carry out an evaluation that includes a user-evaluation among diabetic patients. The evaluation of Ascensia Contour was done under the direction of SKUP during the spring of 2004.

The aim of the evaluation

The aim of the evaluation of Ascensia Contour was to

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

Materials and methods

76 diabetic patients took part in the evaluation. Three different lots of test strips were used. 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 sampling and measurement procedures were repeated, and in addition a sample for hematocrit was taken. Finally, the diabetic patients filled in questionnaires about user-friendliness of the meter and about the user manual.

Results

- Ascensia Contour showed acceptable precision. The CV was < 5 % under standardised and optimal measuring conditions and approximately 5 % when the measurements were performed by diabetic patients.
- The agreement with a designated comparison method was good on certain conditions. Quality goals set in ISO 15197 (± 20 %) and by ADA (± 10 %) were achieved under standardised and optimal measuring conditions when using the first measurement of paired results. The second measurement in the pair was systematic higher than the first. When handled by the diabetic patients, Ascensia Contour showed good results initially and the quality goal set by ISO was attained. After three weeks of use at home the results were not as good as the initial ones. Only 80 % of these results were within the quality goals set by ISO and 90 % were within an "adjusted ISO-goal". It is not clear why these results did not meet the quality goals.
- The three lots of test strips showed no clinical significant bias from the comparison method.
- Glucose measurements on Ascensia Contour seemed to be affected by the hematocrit values of the samples in a higher degree than described in the package insert. The glucose values were

over-estimated when hematocrit was low and under-estimated when hematocrit was high. The hematocrit effect applies not only for high glucose values in combination with high hematocrit values, as described in the package insert, but is also true for glucose values below 11,1 mmol/L and for hematocrit values within the reference range. Although affected by hematocrit, the results achieved under standardised and optimal conditions were within ±15 % of the comparison method.

- The diabetic patients summarised 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.

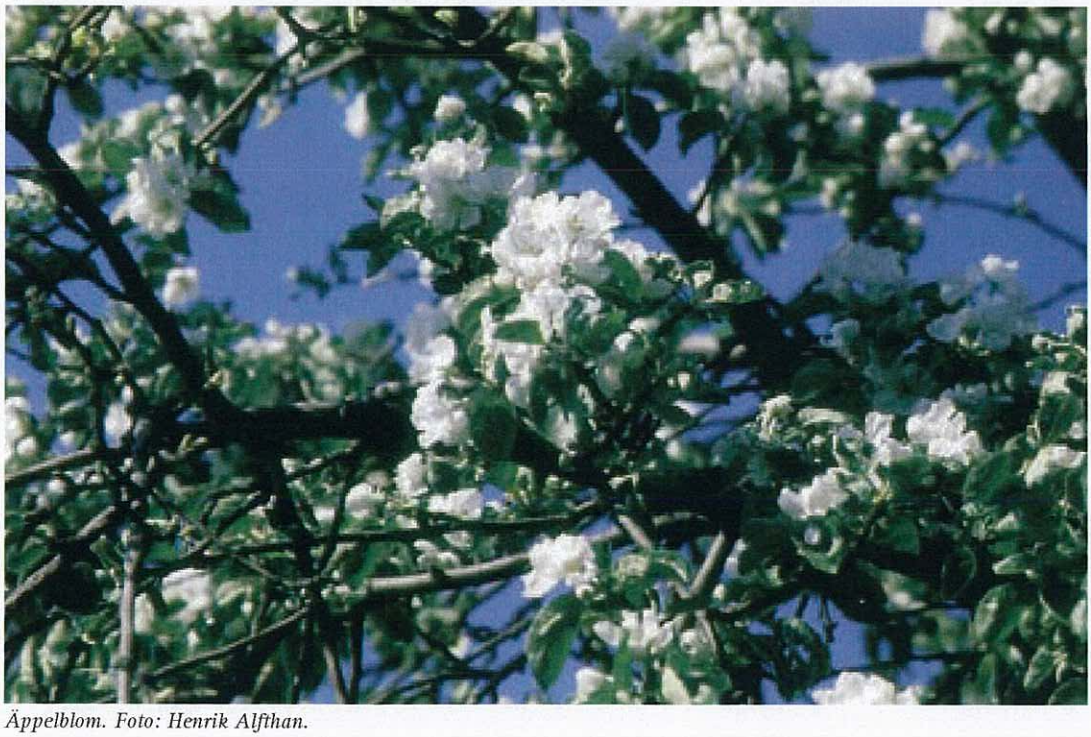
Conclusion

Glucose measurements on Ascensia Contour have acceptable precision. The results obtained under optimal measuring conditions are within the strict quality goals for total error set by ADA. The measurements performed by the diabetic patients initially, when the device was 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 conclude 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 as an attachment to the report. The comments from Bayer are followed by an answer from SKUP.

The complete evaluation report is available at www.skup.nu and is recommended to get further insight in the complexity of the findings in this evaluation.



Äppelblom. Foto: Henrik Alfthan.