Precision Xtra Plus (G3c) glucose

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Summary of an evaluation organised by SKUP

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The complete report, with comments from Abbott, is available at www.skup.nu

Background for the evaluation

The Precision-system from Abbott is designed for glucose self-measurements by diabetics. The Precision Xtra Plus (G3c) is the third generation test strip from Abbott with "True Measure Technology". In this evaluation the test strip was used together with the Precision Xceed meter. The G3c test strip was launched onto the Norwegian market in February 2007.

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 diabetics. The results in the evaluation must meet the quality goals recommended in ISO 15197.

The user-evaluation of Precision Xtra Plus test strip (G3c) was organised by SKUP during the winter of 2005/2006. A supplementary user-evaluation was done during the summer of 2006.

The aim of the evaluation

The aim of the evaluation was to

- reflect the analytical quality under standardised and optimal conditions, performed by trained laboratory staff
- reflect the analytical quality by the users
- 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 user-friendliness and the user-manual

Materials and methods

The evaluation of Precision Xtra plus test strip has been performed twice and includes a complete user-evaluation and a supplementary user-evaluation.

Precision Xtra Plus strips are calibrated to the Yellow Springs Instruments (YSI), while the designated comparison method is a hexokinase based method. According to Abbott Diabetes Care (ADC) the YSI method is known to report lower plasma glucose results than hexokinase based methods. The difference is estimated to be between 4 and 8 %, or even 10 %.

In the first user-evaluation SKUP pointed out a negative bias between 8 and 18 % for Precision Xtra Plus compared to the comparison method. According to the initial response from ADC regarding the preliminary report, the three lots of test strips that were used in the evaluation were amongst the very first batches manufactured, and a drop in the accuracy had been observed in clinical studies as part of ADC's standard Post Market Surveillance Programme. The reported negative bias was reduced by a calibration adjustment applied in manufacturing all subsequent lots. Abbott wanted to have a supplementary user-evaluation performed with three lots of test strips with improved analytical quality.

Analytical quality goals

ISO 15197 recommend the following minimum acceptable accuracy requirement:

Ninety-five percent of the individual glucose results shall fall within ± 0,83 mmol/L of the results of the comparison method at glucose concentrations < 4,2 mmol/L and within ± 20 % at glucose concentrations ≥ 4,2 mmol/L.

This is a quality goal for measurements made by trained laboratory staff. Ideally, the same quality requirements should apply to measurements performed by the diabetics. Previous investigations under the direction of the NOKLUS-project "Diabetes-Self-measurements" showed that few of the self-monitoring glucose meters tested at the

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time met the ISO-requirements. Subsequent SKUP-evaluations confirmed this. As a consequence, the results by the diabetics have been discussed towards a modified goal suggested by NOKLUS, with a total error of ± 25 %. This modified goal has wide, and not ideal, limits. The intention was to tighten up the modified requirements for the diabetics over time, as the meters would hopefully improve due to technological development. More recent evaluations performed by SKUP clearly show that the quality goals set by ISO 15197 now can be achieved also by the diabetics. But for the time being, the quality demands adjusted to the diabetics' self-measurements, still apply.

The evaluation model

77 diabetics took part in the first evaluation and 81 diabetics participated in the supplementary evaluation. In the first evaluation, 40 of the participants had two consultations (the "training group") and the rest had one consultation (the "mail group"). The diabetics in the training group were given a standardised instruction about the Precision-system before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also took samples from a finger capillary of the diabetics and measured twice with the system. In addition, two samples from a finger capillary were taken to a designated comparison method. The diabetics in the mail group received the Precision-system by mail 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 of Precision Xtra Plus/Precision Xceed and the user-manual of Precision Xceed.

For the supplementary evaluation 48 diabetics were recruited from the first user-evaluation and 33 diabetics were recruited through Sørlandet Hospital. The diabetics in the supplementary evaluation had only one consultation. The measuring procedure was similar to the procedure in the first user-evaluation.

Results

The results from the first user-evaluation are only presented in an attachment to the report.

The results from the supplementary user-evaluation:

- Under standardised and optimal measuring conditions, the repeatability CV of Precision Xtra Plus on Precision Xceed was approximately 6 %. The imprecision was a little higher for glucose concentrations < 7 mmol/L. When measured by the diabetics, the precision was acceptable with a CV of approximately 5 % for glucose concentrations > 7 mmol/L. As a whole the imprecision was not significantly higher than 5 %.
- The Precision Xtra Plus showed slightly higher glucose results than the comparison method. The positive bias was approximately 4 to 5 % for glucose values < 10 mmol/L. The bias is statistical significant, but the deviation from the comparison method is hardly of any importance. The negative bias that was pointed out in the first evaluation was more than compensated.
- Two of the three lots of test strips showed significantly higher values than the comparison method. The deviation was approximately 4 %.
- The quality goal set in the ISO 15197 was achieved under standardised and optimal measuring conditions as well as by the diabetics.
- Glucose measurements at Precision Xtra Plus test strips at Precision Xceed did not seem to be affected by hematocrit values between 35 and 49 %.
- The diabetics summarised the Precision-device as easy to use. The diabetics that had used the user manual were satisfied with the manual.

Conclusion

The imprecision of Precision Xtra Plus test strips at Precision Xceed under standardised and optimal measuring conditions and in use by the diabetics was just above 5 % as a whole. Glucose results at Precision Xtra Plus were approximately 4 to 5 % higher than at the comparison method for glucose values < 10 mmol/L. The quality goal set in the ISO-guide 15197 was achieved under standardised and optimal measuring conditions as well as by the diabetics. The glucose measurements did not seem to be affected by hematocrit-values between 35 and 49 %. The users found the Precision-device easy to use.