Multi-site Evaluation of Point of Care Glucose Meters in a Neonatal Intensive Care Unit

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Introduction

Rapid and accurate monitoring of blood glucose levels in a neonatal intensive care setting is important in managing glycemic control. Blood glucose meters developed for self-monitoring of diabetics are commonly used for glucose measurements in hospitalized patients. However recent studies have highlighted that abnormal hematocrit levels, which are commonly found in neonates, can adversely influence the accuracy of currently used glucose meters.

StatStrip® Glucose (Nova Biomedical) is a new generation handheld glucose sensor specifically designed for hospital use. The design of the sensor corrects for common biochemical interference factors and also measures and corrects for hematocrit.

Aim

• To assess the analytical performance, accuracy and specificity of the StatStrip® Glucose sensor in four different neonatal intensive care settings in Europe and North America.
• To compare the performance of StatStrip® Glucose to glucose meters routinely used in these settings.
• To compare results with established international quality standards for glucose measurements ISO 15197 and TNO (Netherlands Organisation for Applied Scientific Research) approved protocol for glucose meter measurements.

Method

Glucose Methods Used
• StatStrip® (Nova Biomedical)
• Advantage® (Roche Diagnostics)
• Optium Xceed® (Abbott Diabetes),
• Contour® (Bayer Healthcare).
• AccuChek Inform (Roche Diagnostics)
• Precision PCx® (Abbott Diabetes)
• Aviva® (Roche Diagnostics),
• Precision Freestyle® (Abbott Diabetes),
• SureStep Flexx® (LifeScan),

Comparison Methods Used
• Hitachi 912 analyzer (Roche Diagnostics)
• Aeroset analyser (Abbott Diagnostics)
• ABL 735 (Radiometer)
• RapidLab 1265 Blood gas analyzer (Siemens)

Hematocrit interference

Hematocrit interference was evaluated using 5 glucose concentrations over a hematocrit range of 20-70%.

NICU assessment

Whole blood samples were collected from neonatal intensive care patients and tested on the respective meters. The glucose meter results were compared with the central laboratory hexokinase method or blood gas analyzer. Hematocrit levels were determined for each patient.
Results

StatStrip® Method Correlation

StatStrip® correlated well with the routine laboratory or blood gas analyzer methods used in each study site.

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Hematocrit Interference

The accuracy of the meters routinely used was affected to varying degrees by abnormal hematoctrit level readings showing significant bias compared to the reference method. The accuracy of StatStrip® was unaffected by varying hematocrit levels.

Site B - Hematocrit interference study
Results (Cont’d)

Bias plot analysis of the influence of patient hematocrit levels on meter accuracy also showed that StatStrip® readings were unaffected by varying hematocrit levels.

Site D - Hematocrit interference study

Site C - Hematocrit interference study
Results (Cont'd)

**NICU Accuracy – ISO15197 criteria**

In all four study sites StatStrip® demonstrated greater accuracy compared to the routine meters used with results meeting the requirements of ISO 15197 criteria.

Site A – Accuracy assessment

NICU Accuracy – TNO criteria

StatStrip® achieved the requirements of the TNO protocol

Site B - Accuracy assessment

NICU Accuracy – ISO15197 criteria
Results (Cont’d)

NICU Accuracy ≤ 4.2 mmol/L range

Analysis of consolidated study data demonstrates that StatStrip® glucose has good accuracy at a glucose range ≤ 4.2 mmol/L meeting the requirements of ISO 15197 (97.2% of values meeting criteria of ISO 15197)

Conclusion

• StatStrip® Glucose which is specifically designed to compensate for hematocrit and chemical interferences, was shown to provide the most accurate and reliable results for glucose measurements in NICU patients.
• The performance of StatStrip® Glucose was unaffected by the wide range of hematocrit levels found in NICU patients.
• StatStrip® Glucose met the criteria of established international quality standards for glucose measurements (ISO 15197 and TNO).