

Assessment of the performance of Blood Glucose Monitoring Systems for monitoring dysglycaemia in neonatal patients.

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Introduction

In China there has been little validation of the wide range of mainly self-monitoring blood glucose meters used in hospitals. Interest is now growing in ensuring accurate blood glucose measurements are obtained that enable safe and effective decision making for managing dysglycaemia. It is recognised that any evaluation should include an IDMS aligned laboratory reference method. The aim of this study was to establish an IDMS traceable reference method and to utilise this to undertake an analytical and clinical evaluation of BGMS.

Methods

The calibration of the laboratory glucose oxidase reference method (Hitachi 7180) was verified using aqueous glucose samples prepared from primary NIST standard 917c and liquid protein glucose samples prepared from secondary NIST standard 965b. For the analytical study method correlation and precision studies were performed on whole blood venous samples. A specificity study was also undertaken looking at the influence of interfering factors such as ascorbic acid, lactose, galactose, β -hydroxybutyrate, N-acetylcysteine and glutathione as well as with different haematocrit levels (19.8-65.5%) on the accuracy of glucose measurements across different glucose levels. The BGMS tested included AccuChek Inform 2 (Roche) and StatStrip Glucose (Nova Biomedical). For the clinical study heel stick capillary samples were collected from new born babies and included well babies as well as neonates admitted to intensive care.

Results

The laboratory reference method achieved the target glucose values for the NIST standards with a low mean % bias across the range of -2.8% to -2.6%. Both BGMS demonstrated good within day precision with the range of glucose values tested. Both BGMS also showed a good correlation to the ID-LCMS aligned reference method. For both BGMS two different meters and strip lots were assessed, for StatStrip the linear regression analysis was $y = 0.915 + 0.249x$ with an r^2 of 0.995 and $y = 0.905 + 0.266x$ with an r^2 of 0.997. For AccuChek Inform 2 the linear regression analysis was $y = 0.907 + 0.331x$ with an r^2 of 0.997 and $y = 0.898 + 0.350x$ with an r^2 of 0.997. Varying levels of haematocrit did not affect the accuracy of both BGMS. In addition the accuracy of both BGMS was not affected by β -hydroxybutyrate levels tested. None of the other interfering factors influenced the accuracy of StatStrip Glucose measurements. The accuracy of AccuChek Inform 2 glucose measurements were affected by ascorbic acid, lactose, galactose, N-acetylcysteine and glutathione with moderate to significant interference observed. Initial testing of neonatal capillary samples show that StatStrip Glucose correlates well with laboratory reference method. Data will be presented at the meeting.

Conclusion

The laboratory glucose oxidase method used in our hospital is IDMS traceable and as such is validated for undertaking an evaluation of the accuracy of blood glucose monitoring systems. Both BGMS tested showed good analytical performance but the specificity of AccuChek Inform 2 is affected by a number of interfering factors that can be present in the matrix of hospitalised and in particular critically ill patients.