Continuous glucose monitoring in newborn infants: How do errors in calibration measurements affect detected hypoglycaemia

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Introduction: Neonatal glycaemia is highly variable and can cause serious brain injury if uncontrolled [1]. However, monitoring infants' blood glucose (BG) levels via frequent BG measurements is not achievable due to a lack of blood and the distressed caused to both mother and child. Hence, the risk of neonatal hypoglycaemia is yet to be negated. Continuous glucose monitoring (CGM) could improve hypoglycaemia detection, while reducing the number of BG measurements [2]. CGM and BG are not necessarily well correlated, and this research aims to quantify the effect of timing delays and calibration errors on the risk of hypoglycaemia in newborn infants.

Methods: Data from 155 babies were used. Two timing error models and three BG meter error models (Abbott Optium Xceed, Roche Accu-chek Inform II, Nova Statstrip) were created using empirical data. Monte-Carlo methods were employed and each simulation was run 1000 times. Each set of patient data in each simulation had randomly selected timing and/or measurement error added to BG measurements before CGM data were calibrated. The number of hypoglycaemic events, duration of hypoglycaemia and hypoglycaemic index were then calculated using the CGM data and compared to baseline values.

Results and Discussion: Timing error alone had little effect on hypoglycaemia metrics, but measurement error caused substantial variation. Abbott results under reported the number of hypoglycaemic events by up to 8 and Roche over reported by up to 4. Nova results were closest to baseline. Similar trends were observed in the other hypoglycaemia metrics.

Errors in blood glucose concentration measurements used for calibration of CGMs can have a clinically important impact on detection of hypoglycaemia. This error in calibration increases the danger of incorrect treatment of neonatal hypoglycaemia. Overall, if CGMs are going to be used clinically for assessing events such as hypoglycaemia it is important to understand of the impact of these errors can have on CGM data.

1. Stanley, C.A. and L. Baker, *The causes of neonatal hypoglycemia.* New England Journal of Medicine, 1999. **340**(15): p. 1200-1201.
2. Harris, D.L., et al., *Continuous Glucose Monitoring in Newborn Babies at Risk of Hypoglycemia.* Journal of Pediatrics, 2010. **157**(2): p. 198-202.