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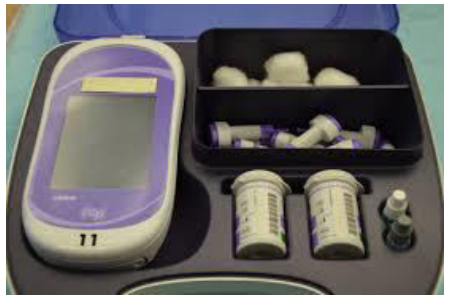
What's new with devices, glucometers and Continuous Glucose Monitoring systems

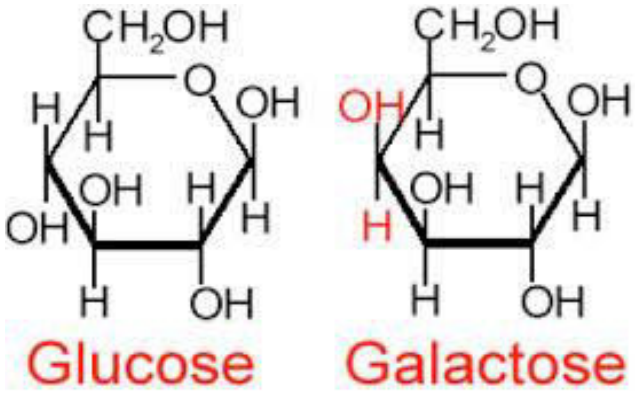
Madhini Sivasubramanian


Reflolux S
FreeStyle


11.9
Before meal
After meal
ACCU-CHEK
10.8
mmol/L
OK
11.2
FreeStyle InsuLinx



Current blood glucose monitors licenced but measures Galactose



galactose severe (34%) positive interference

Ref: Freyman et. al. 2010. Annals of Clinical Biochemistry Volume 47 September 2010

Continuous Glucose Monitors

- A **continuous glucose monitor** is a device used for monitoring glucose levels on a continual basis. A continuous glucose monitor (CGM) takes a reading on set intervals with a small electrode placed under the skin and held in place by an adhesive. A transmitter attached to the electrode sends data to a separate receiver.
- Traditional finger prick testing of blood glucose levels measures the level at a single point in time. CGM use allows trends in blood glucose to be displayed over time. Users must calibrate CGM devices with traditional blood glucose measurements.
- A limitation of the CGM system is that glucose levels are taken from the interstitial fluid rather than the blood. There is an inherent lag behind the current blood glucose level and the level measured by the CGM. - is generally 5–20 minutes.

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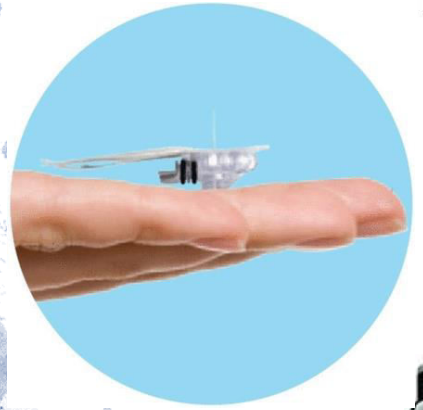
CGMS
Medtronic

The Enlite sensor



Guardian 2 Link Transmitter

The MinMed 640G Device

Abbotts FreeStyle Libre

CGMS
Dexcom

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Dexcom G6 app*
or Receiver

Transmitter

Applicator
with Sensor

How Dexcom SHARE® Works

Dexcom G6 app

Dexcom Follow app

For a list of compatible devices visit dexcom.com/compatibility
Separate Follow app required

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“NO FINGERSTICKS. BEST. NEWS. EVER.”

Anita V - T1D

The Dexcom G6 Continuous Glucose Monitoring (CGM) eliminates finger sticks for calibration and treatment decisions.*

*If your glucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make treatment decisions.

Holden and Zola,
T1Ds

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Approved for 2+ Years

The only CGM FDA-approved for ages two years and older

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Open Access Protocol

BMJ Open

Protocol of a randomised controlled trial of real-time continuous glucose monitoring in neonatal intensive care 'REACT'

Kathryn Beardsall,[1,2] Lynn Thomson,[1,2] Catherine Guy,[1] Mirjam M van Weissenbruch,[3] Isabel Iglesias,[4] Priya Muthukumar,[5] Sateesh Kumar Somisetty,[6] Simon Bond,[7] Stavros Petrou,[8] David Dunger,[1] REACT Investigators

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ABSTRACT

Introduction Hyperglycaemia is common in the very preterm infant and has been associated with adverse outcomes. Preventing hyperglycaemia without increasing the risk of hypoglycaemia has proved challenging. The development of real-time continuous glucose monitors (CGM) to inform treatment decisions provides an opportunity to reduce this risk. This study aims to assess the feasibility of CGM combined with a specifically designed paper guideline to target glucose control in the preterm infant.

Methods and analyses The Real Time Continuous Glucose Monitoring in Neonatal Intensive Care (REACT) trial is an international multicentre randomised controlled trial. 200 preterm infants ≤1200 g and ≤24 hours of age will be randomly allocated to either real-time CGM or standard care (with blinded CGM data collection). The primary outcome is time in target 2.6–10 mmol/L during the study intervention assessed using CGM. Secondary outcomes include efficacy relating to glucose control, utility including staff acceptability, safety outcomes relating to incidence and prevalence of hypoglycaemia and health economic analyses.

Ethics and dissemination The REACT trial has been approved by the National Health Service Health Research Authority National Research Ethics Service Committee East of England (Cambridge Central); Medical Ethics Review Committee, VU University Medical Centre

Strengths and limitations of this study

- The comparison of real-time continuous glucose monitoring (CGM) data with blinded CGM data in the control study arm will provide detailed comparable data on efficacy and safety between study arms.
- As an international multicentre trial, the results will be generalisable across a range of neonatal intensive care settings.
- Input by staff and parents within the trial itself as well as part of the trial management will provide information on utility and facilitate translation of the outcomes into clinical practice.
- The study requires recruitment within 24 hours of preterm birth which requires a significant commitment from the clinical and research teams if it is to be successful.
- The study is powered to detect a difference in the primary outcome 'time in target' (2.6–10 mmol/L), but will not have the power to detect the impact on clinical outcomes.

born preterm are at risk of both hyperglycaemia and hypoglycaemia.[2] Hyperglycaemia and hypoglycaemia have both been associated with increased mortality and morbidity

Licenced monitors for use in neonates?

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McKinlay *et al. Maternal Health, Neonatology, and Perinatology* (2017) 3:18
DOI 10.1186/s40748-017-0055-z

Maternal Health, Neonatology, and Perinatology

REVIEW Open Access

Continuous glucose monitoring in neonates: a review

Christopher J.D. McKinlay[1,2*], J. Geoffrey Chase[3], Jennifer Dickson[3], Deborah L. Harris[1,4], Jane M. Alsweiler[1,2] and Jane E. Harding[1]

Abstract

Continuous glucose monitoring (CGM) is well established in the management of diabetes mellitus, but its role in neonatal glycaemic control is less clear. CGM has provided important insights about neonatal glucose metabolism, and there is increasing interest in its clinical use, particularly in preterm neonates and in those in whom glucose control is difficult. Neonatal glucose instability, including hypoglycaemia and hyperglycaemia, has been associated with poorer neurodevelopment, and CGM offers the possibility of adjusting treatment in real time to account for individual metabolic requirements while reducing the number of blood tests required, potentially improving long-term outcomes. However, current devices are optimised for use at relatively high glucose concentrations, and several technical issues need to be resolved before real-time CGM can be recommended for routine neonatal care. These include: 1) limited point accuracy, especially at low or rapidly changing glucose concentrations; 2) calibration methods that are designed for higher glucose concentrations of children and adults, and not for neonates; 3) sensor drift, which is under-recognised; and 4) the need for dynamic and integrated metrics that can be related to long-term neurodevelopmental outcomes. CGM remains an important tool for retrospective investigation of neonatal glycaemia

There is no validated study on the use of CGM in children or infants with CHI; however some literature can support its use.

Saw (2017) - studied thirty infants of diabetic mothers, concluding that CGM provided real time information with high sensitivity and specificity

RESEARCH ARTICLE

The value of real-time continuous glucose monitoring in premature infants of diabetic mothers

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Abstract

To determine the feasibility of using a real-time continuous glucose monitoring system (RTGMS) in intensive care units, our study focus on preterm infants with diabetic mothers owing to their high risk of blood sugar abnormalities. Thirty preterm babies ($M = 15$ and $F = 15$; ≤ 36 week gestation age) were studied from within 72 hours of delivery. These babies were admitted to the newborn intensive care and were further categorized into groups based on whether their mothers with or without diabetic mellitus. Blood sugar levels were monitored by both RTGMS and the traditional intermittent arterial line (A-Line) glucose method. Continuous glucose monitoring were well tolerated in 30 infants. There were good consistency between RTGMS and A-Line glucose concentration measurements. Of the pre-term infants, 33.33% experienced abnormal glucose levels (hypoglycemia or hyperglyce-

There is no validated study on the use of CGM in children or infants with CHI; however some literature can support its use.

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Harris (2010) – studied one hundred and two neonates, reporting that CGM detected additional hypoglycaemic episodes which would have been undetected if only conventional bed side blood glucose monitoring had been used.

Continuous Glucose Monitoring in Newborn Babies at Risk of Hypoglycemia

Deborah L. Harris, MHSc (Hons), Malcolm R. Battin, MBChB, Philip J. Weston, MBChB, and Jane E. Harding, MBChB

Objective To determine the usefulness of continuous glucose monitoring in babies at risk of neonatal hypoglycemia.
Study design Babies ≥32 weeks old who were at risk of hypoglycemia and admitted to newborn intensive care received routine treatment, including intermittent blood glucose measurement using the glucose oxidase method, and blinded continuous interstitial glucose monitoring.
Results Continuous glucose monitoring was well tolerated in 102 infants. There was good agreement between blood and interstitial glucose concentrations (mean difference, 0.0 mmol/L; 95% CI, -1.1–1.1). Low glucose concentrations (<2.6 mmol/L) were detected in 32 babies (32%) with blood sampling and in 45 babies (44%) with continuous monitoring. There were 265 episodes of low interstitial glucose concentrations, 215 (81%) of which were not detected with blood glucose measurement. One hundred seven episodes in 34 babies lasted >30 minutes, 78 (73%) of which were not detected with blood glucose measurement.
Conclusion Continuous interstitial glucose monitoring detects many more episodes of low glucose concentrations than blood glucose measurement. The physiological significance of these previously undetected episodes is unknown. *(J Pediatr 2010;157:198-202).*

See editorial, p 180

Neonatal hypoglycemia was first identified as a common condition causing brain damage and death in 1937.[1] Now more than 70 years later, there is a paucity of data underpinning clinical practice, and the best way to diagnose and treat neonatal hypoglycemia remains unclear.

Blood glucose concentrations fluctuate after birth as the baby adapts to extra-uterine life,[2] and are normally measured intermittently. This means that episodes of hypoglycemia may go undetected, and their duration and severity cannot be assessed.

There is no validated study on the use of CGM in children or infants with CHI; however some literature can support its use.

Senniappan et al (2018) – studied 11 children with CHI using CGM –FSL Freestyle Libre, reporting that larger trials are needed in CHI patients. They found that parents find the glucose trend to be very useful.

Alsaffar *et al. International Journal of Pediatric Endocrinology* (2018) 2018:3
https://doi.org/10.1186/s13633-018-0057-2

International Journal of Pediatric Endocrinology

RESEARCH Open Access

Continuous Flash Glucose Monitoring in children with Congenital Hyperinsulinism; first report on accuracy and patient experience

Hussain Alsaffar[1], Lucy Turner[2], Zoe Yung[2], Mohammed Didi[2] and Senthil Senniappan[2*]

Abstract

Background: The factory calibrated FreeStyle Libre (FSL) flash glucose monitoring system has been recently introduced for use in patients with diabetes mellitus. There are no reports available regarding its use in patients with congenital hyperinsulinism (CHI). We have assessed the accuracy of FSL compared to the finger prick capillary blood glucose (CBG) over 2 weeks period in patients with CHI and evaluated the parents' experience of using FSL.

Methods: Four hundred sixty-seven episodes of CBG along with corresponding swipe FSL readings were available from 11 children with CHI (0.5–5 years). A detailed questionnaire was completed by the parents.

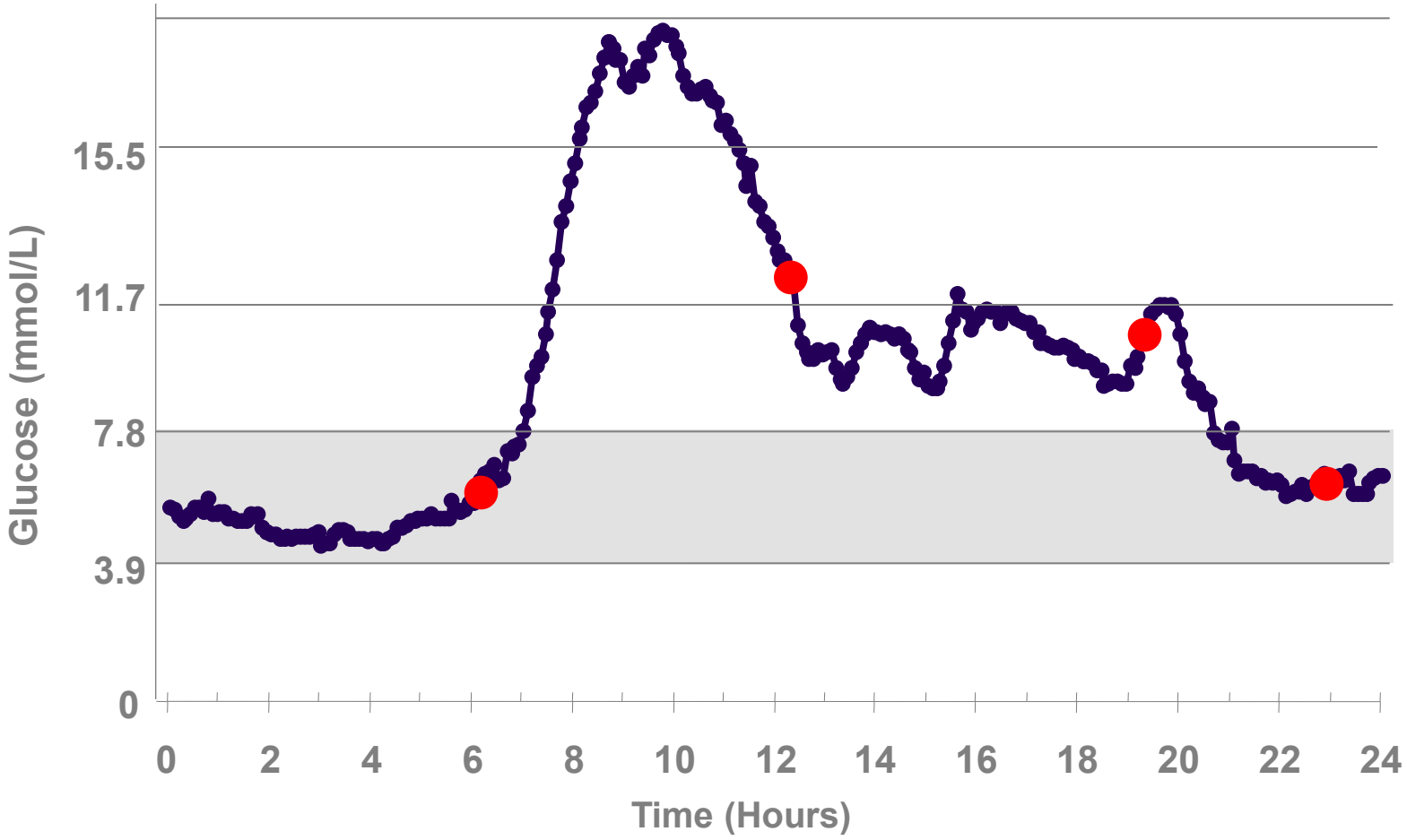
Results: The mean variation between the two methods was 0.29 mmol/l (SD ±1.07), higher readings by FSL compared to CBG. The FSL sensors stayed in-situ for an average period of 11.5 days. There was a positive correlation between the two methods ($r = 0.7$). The FSL tended to overestimate compared to CBG (bias =0. 29 mmol/l; 95% CI: 0.19 to 0.38). Only 70% of values were within the reference standard (±0.83 mmol/l) at glucose concentrations less than 5.6 mmol/l. The overall Mean Absolute Relative Difference (MARD) was 17.9%. Forty two episodes of hypoglycaemia (CBG < 3.5 mmol/l) were noted but FSL identified only 52% of these episodes. The Bland Altman analysis showed the 95% limits of agreement between the two methods ranging from − 1.8 (95% CI: -1.97 to − 1.64) to 2.37 (95% CI: 2.21 to 2.54). Majority of the parents found the glucose trend on FSL to be useful to detect and prevent hypoglycaemic episodes. All parents felt that FSL is a very easy and convenient method to measure the glucose especially during sleep. A significant proportion of parents felt that FSL readings were not accurate and 56% of parents expressed interest to continue using FSL after the trial period.

Conclusion: Noticeable variability between the two methods of measuring the glucose was noted. Despite the ease of using the FSL system, concerns related to accuracy, especially at low glucose values do remain although parents find the glucose trend to be very useful. Further larger trials are needed in CHI patients before FSL is recommended as a routine alternative method for measuring glucose levels.

NICE Guidelines

- The technology of real-time continuous glucose monitoring (CGM) has been developed for the diabetes population with dramatic results, leading to better control of blood glucose levels, less frequent monitoring and improved quality of life, (Philip et al., 2012).
- The quality statement, from the National Institute of Clinical Excellence (NICE) on the use of CGM in type 1 diabetes outlines that,
- **“Those children and young people who have frequent, severe hypoglycaemia are offered ongoing real-time continuous glucose monitoring with alarms.” (NICE, 2015).**
- **“The rationale is that a CGM improves blood glucose control and is valuable for those patients who have difficulty recognising hypoglycaemic episodes” (NICE, 2015).**

BGM vs. CGM


Glucose (mmol/L)
15.5
11.7
7.8
3.9
0
0
2
4
6
8
10
12
14
16
18
20
22
24
Time (Hours)

Advantages and Disadvantages of using CGMS

- Track your Blood sugar levels all through the day and night
- You can see trends, graphs…and take action earlier
- You don’t need to do so many finger pricks
- You can set it to alarm at high and low levels

- Data Overload which can confuse or worry you
- You still need to do some finger pricks
- You may find wearing the CGMS irritating or unsightly
- You need to be motivated to use the data it gives you to get the best blood glucose management.

Acknowledgement

- Patients and familes
- GOSH CHI Team(Dr Pratik Shah, CNS's-Clare Gilbert, Kate Morgan, Louise Doodson and Hannah Antell)
- Prof Nick Oliver
- Great Ormond Street Hospital Children's Charity

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Thank you

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