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Safety and feasibility of a factory-calibrated continuous glucose monitoring system in term and near-term infants at risk of hypoglycemia

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What is already known on this topic?

- *A continuous glucose monitoring system using factory-calibrated sensors was recently approved for diabetes management in persons aged ≥18 years. Although it has reasonable accuracy and usefulness in children with type 1 diabetes, there are no reports on its safety and feasibility in newborn infants.*

What this study adds on this topic?

- *Values from this continuous glucose monitoring system were compared with blood glucose concentrations in term and near-term infants at risk of hypoglycemia after delivery. This system was a safe and feasible method for glucose control but had a tendency to overestimate the blood glucose concentrations. We should use this system cautiously for neonates at risk of hypoglycemia, especially within 3 hours after sensor placement.*

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ABSTRACT

Objective: Hypoglycemia increases the risk of adverse neurological outcomes in neonates. Adequate glucose monitoring requires repetitive and painful blood sampling. We aimed to evaluate the feasibility and accuracy of a continuous glucose monitoring system (CGMS) using factory-calibrated sensors to improve glucose monitoring and decrease the frequency of blood samples in neonates.

Material and Methods: A methodological study was conducted to investigate a correlation of CGMS values with blood glucose measurements.

Results: Factory-calibrated CGMS sensors were placed on 21 infants at risk of hypoglycemia after delivery. CGMS values were compared with blood glucose concentrations. Thirty-seven pairs of CGMS and blood glucose values were obtained. There was a good correlation between CGMS and blood glucose values (R=0.67, p<0.01) with a mean difference (2 standard deviations) of 9.78 (−24.68 to 44.25) mg/dL. The mean differences at <3 hours and ≥3 hours after sensor placement were 17.35 (−4.54 to 39.21) mg/dL and 0.88 (−37.62 to 39.38) mg/dL, respectively. CGMS values were significantly higher than blood glucose concentration at <3 hours after sensor placement (p<0.01), whereas no significant differences in glucose values were observed between the CGMS and blood glucose values at ≥3 hours after sensor placement (p=0.852).

Conclusion: The factory-calibrated CGMS was a safe and feasible modality for glucose monitoring. However, it has a tendency to overestimate the blood glucose concentrations. Therefore, this system should be used cautiously for neonates at risk of hypoglycemia, especially within 3 hours after sensor placement.

Keywords: Blood glucose, blood glucose self-monitoring, hypoglycemia, neonate

Introduction

Hypoglycemia is the most frequently occurring metabolic disturbance in the neonatal period, and its major risk factors in neonates are prematurity, perinatal stress or asphyxia, small for gestational age (SGA), large for gestational age (LGA), and being born to a mother with diabetes (1-3). Severe and persistent hypoglycemia can cause seizures and brain injury. Recent population-based studies revealed that exposure to even brief, mild, or moderate asymptomatic hypoglycemia may permanently impair brain development and later learning (4). Therefore, defining the group of neonates at high risk of hypoglycemia to enable immediate treatment and prevention of adverse neurological outcomes are very important (5, 6). To avoid hypoglycemia, it is necessary to monitor and control the blood glucose level, which re-

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quires frequent blood sampling, exposing neonates to repeated pain and stress and, as has been reported, increasing the risk of negative neurological outcomes during this vulnerable phase of brain development (7). Intermittent blood sampling carries the risk of hypoglycemia occurring in between samples, so continuous blood glucose monitoring by continuous glucose monitoring system (CGMS) could be useful.

CGMS has high reliability in monitoring blood glucose levels in children with type 1 diabetes mellitus (8) and, as indicated in few studies, is a safe tool in estimating glucose homeostasis in critically ill children (9-13). Currently, most commercially available CGMSs require frequent calibration using capillary blood samples obtained using a finger stick or a lateral heel stick. An initial calibration is always needed, and recalibrations are typically necessary every 12 hours (14). Despite great advances in the technology, devices currently used are not designed for use in neonates, and there are technical challenges with using devices in the neonate, including (1) insertion methods, (2) accuracy, and (3) clinical interpretation (15).

In 2017, the stand-alone non-adjunctive factory-calibrated flash FreeStyle Libre (Abbott Diabetes Care, Alameda, CA, USA) CGMS was first approved by the Food and Drug Administration for the management of diabetes in persons aged ≥18 years (16). It has reasonable accuracy and usefulness in children with type 1 diabetes (17-19). However, there are no reports on its safety and feasibility in newborn infants. Therefore, in this study, we evaluated the accuracy of this device in term and near-term infants at risk of hypoglycemia compared with the accuracy of blood glucose measurements with the clinical aims of increasing patient safety by improving glucose monitoring while reducing procedural pain.

Material and Methods

Study population

This methodological study was performed at the newborn nursery at Saitama Medical Center, Saitama Medical University, Kawagoe, Saitama, Japan, between October 2018 and March 2019. All infants of gestational age >35 weeks and birth weight >2,000 g were included if they needed blood glucose measurements because of a high risk of hypoglycemia. Thus, infants born with SGA or LGA, prematurely (<37+0 weeks), and to mothers with diabetes and infants with signs of infection or perinatal asphyxia were included. Infants with SGA and LGA were defined as those with less than 10th percentile and those with more than 90th percentile, respectively, for birth weight on the basis of gestational age and sex.

The exclusion criteria included those with any severe skin lesions. Written informed consent was obtained from parents, and the study protocol was approved by the Ethics Committee of Saitama Medical Center, Saitama Medical University (approval number: 1864, approval date: 3/October/2019). The research was conducted in accordance with the World Medical Association's Helsinki Declaration.

The CGMS device

The FreeStyle Libre System is a stand-alone CGMS device that consists of a reader and a sensor kit, needs no calibration (factory calibrated), and lasts for 14 days (20). The CGMS sensor measures glucose values in the subcutaneous tissue by an enzymatic amperometric three-electrode sensor system (21).

After obtaining parental consent, all infants who met the selection criteria received a subcutaneous sensor and a CGMS device. After local disinfection with ethanol swabs, the sensor was placed into the subcutaneous tissue on the left lateral thigh of each infant using the sensor inserter provided by the manufacturer. We observed the insertion site for signs of infection, bleeding, or dislocation at least three times a day.

Once the sensor was activated by the reader, which scanned it from a distance of 1-4 cm, it took 1 hour for the sensor to adjust to the patient's body and produce accurate readings. All sampling times were recorded as hours and minutes according to the displayed time on the CGMS device.

Reference blood glucose measurements

The blood glucose values were measured from capillary blood samples obtained using a lateral heel stick. After local disinfection with ethanol swabs, the heel stick was performed by nurses or midwives using an infant safety lancet (BD Quikheel, Becton Dickinson Vacutainer Systems, Franklin Lakes, NJ, USA) with a defined penetration depth. The drops of blood were aspirated into the sampling cuvette connected to the StatStrip Xpress (Nova Biomedical, Waltham, MA, USA). Blood glucose measurement using this bedside device allowed instant analysis and minimized the time confidence interval (CI) between sampling and measurement. The clinical assessment and treatment were based only on the blood glucose sample values. Glucose monitoring was performed over the first 2 hours and just before the second feeding of milk after birth and was only continued before each feed as long as the blood glucose values did not reach 50 mg/dL or until patients were transferred to the neonatal intensive care unit for treatment of hypoglycemia.

Statistical analysis

Statistical analysis was performed using the following methods with EZR statistical software (Saitama Medical Center, Jichi Medical University, Saitama, Japan). The correlation between the glucose level measured from the reference blood sample from a heel stick and that from the CGMS were analyzed using Pearson's product-moment correlation and linear regression. The differences between blood glucose and the CGMS values were analyzed using Bland-Altman analysis. The paired Student's *t*-test was used to review the differences in paired values measured from the reference sample of heel stick and CGMS. The correlation between the differences between blood glucose and the CGMS values and time after CGMS placement were analyzed using nonlinear regression. A p-value <0.05 was considered statistically significant.

Results

Patient characteristics

Patients' characteristics are presented in Table 1. Twenty-one term infants (males, 10; females, 11) were included in this study. The median gestational age was 38.1 weeks (interquartile range [IQR]: 37.0–39.1 weeks), and the median birth weight was 2,713 g (IQR: 2,429–3,455 g).

The reasons for being at high risk of hypoglycemia were SGA (n=1, 5%), LGA (n=7, 33%), low birth weight (n=7, 33%), and infant of a mother with diabetes (n=6, 29%). The sensor was placed on a specific site for a median duration of 2.5 hours (IQR: 1.4–4.3 hours). A total of 37 pairs of CGMS values and blood glucose concentrations from lateral heel sticks were obtained.

Representative measurements of blood glucose and CGMS values

Figure 1 shows the results of blood glucose and CGMS measurements from two cases that showed the smallest discrepancies between the CGMS and reference glucose values. Case 1 was a female with a gestational age of 39 weeks and 5 days and a birth weight of 3,123 g who was the infant of a mother with diabetes. Case 2 was a female with a gestational age of 37 weeks and 0 days and a birth weight of 2,169 g who has a low birth weight. The CGMS values were recorded every 15 minutes using the FreeStyle Libre System. In addition, the CGMS values and blood glucose concentrations were measured at the same time according to our institutional protocol, such as at the first 2 hours and just before each feeding of milk after birth. In Case 1 (Figure 1a), at 4 hours and 42 minutes after the CGMS sensor placement, the CGMS value was 72 mg/dL, whereas the blood glucose concentration was 71 mg/dL. In Case 2 (Figure 1b), at 1 hour and 19 minutes after the sensor placement, the CGMS value was 71 mg/dL, whereas the blood glucose concentration was 51 mg/dL. However, at 4 hours and 16 minutes after the sensor placement, the CGMS value was 82 mg/dL, and blood glucose concentration was 80 mg/dL.

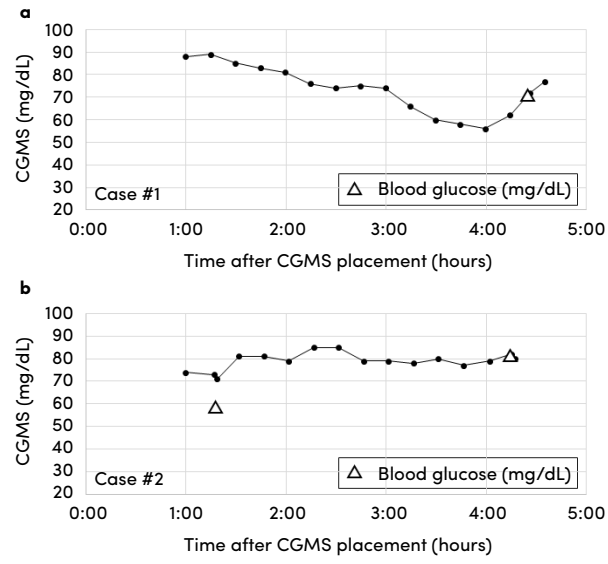

Figure 1. a, b. Representative measurements of CGMS and blood glucose values from two cases (a, Case #1; b, Case #2). A line with a closed circle shows the CGMS values. An open triangle shows the blood glucose concentrations obtained using a lateral heel stick
CGMS, continuous glucose monitoring system

Comparison between CGMS values and blood glucose concentrations

Thirty-seven pairs of CGMS values and blood glucose concentrations from 21 neonates were obtained and their correlations were analyzed using Pearson's product-moment correlation and Bland-Altman analysis (Figure 2). A relatively strong correlation was observed between CGMS values and blood glucose concentrations (R=0.67, p<0.01) (Figure 2a). However, the

Table 1. Patients characteristics

Characteristics	Term infants (n=21)
Gestational age, weeks, median, (IQR)	38.1 (37.0-39.1)
Birth weight, g, median (IQR)	2,713 (2,429-3,455)
Male, n (%)	10 (48%)
APGAR-1, minute, median (IQR)	8 (8-8)
APGAR-5, minutes, median (IQR)	9 (9-9)
Small for gestational age, n (%)	1 (5%)
Large for gestational age, n (%)	7 (33%)
Low birth weight infant, n (%)	7 (33%)
Infants of a mother who is diabetic, n (%)	6 (29%)
Time of data acquisition after CGMS placement, hours, median (IQR)	2.5 (1.4-4.3)
Number of data acquisition per patient, median (IQR)	1.5 (1-2)

APGAR, Appearance, Pulse, Grimace, Activity, and Respiration; CGMS, continuous glucose monitoring systems; IQR, interquartile range

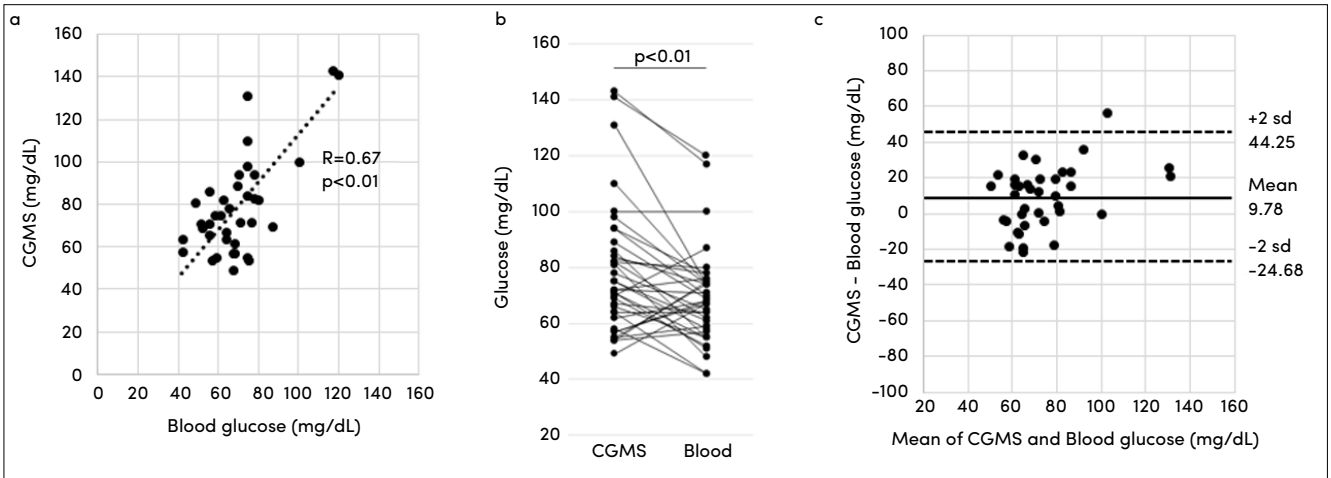

Figure 2. a-c. (a) Correlation between CGMS and blood glucose values. The dotted line shows a linear regression trend line. (b) Difference between CGMS and blood glucose values in each pair of measurements. (c) Bland-Altman plot. CGMS versus blood glucose values. A straight line shows the mean difference between CGMS and blood glucose values, and the two dotted lines show ±2 standard deviations. CGMS: continuous glucose monitoring system

CGMS values were significantly higher than the blood glucose concentrations (p<0.01) (Figure 2b). The mean difference (standard deviation [SD]) between CGMS values and blood glucose concentrations was 9.78 (17.23) mg/dL (Figure 2c).

Time-dependent accuracy of CGMS measurements

To assess the time-dependent accuracy of CGMS measurements, the correlation between time after CGMS placement and differences in glucose concentrations measured from CGMS and the reference blood sample was investigated. A relatively good correlation was observed between time after CGMS placement and differences between CGMS values and blood glucose concentrations (R=0.452, p<0.01) (Figure 3). The shorter the time after CGMS placement, the higher the CGMS values were compared with the reference blood glucose concentrations. Paired sets of data from CGMS and blood samples were divided into two groups, namely data sets obtained within 3 hours after CGMS placement (early sampling group, n=20 pairs) and those obtained beyond 3 hours after CGMS placement (late sampling group, n=17 pairs). CGMS values were higher than blood glucose concentrations in the early sampling group (p<0.01) (Figure 4a), whereas no significant differences in glucose levels were observed between CGMS values and blood concentrations in the late sampling group (p=0.852) (Figure 4b). Mean (SD) differences between CGMS values and blood glucose concentrations in the early and late sampling groups were 17.35 (10.93) mg/dL and 0.88 (19.25) mg/dL, respectively (Figure 4c).

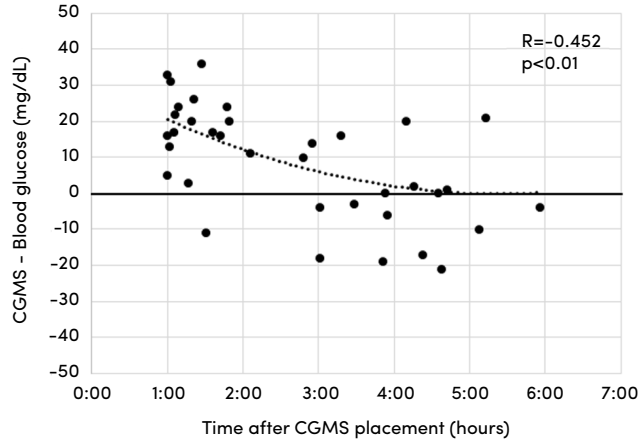

Figure 3. Correlation between the differences between CGMS and blood glucose values and time after CGMS placement. The dotted curve shows a nonlinear regression trend curve
CGMS, continuous glucose monitoring system

Discussion

In this study, factory-calibrated CGMS values showed a relatively good correlation with blood glucose concentration. However, it is not an accurate method of identifying hypoglycemia in term and near-term infants at risk, especially within the first 3 hours after sensor insertion.

After the development of the first device for reading blood glucose levels continuously, which was approved by the Food and Drug Administration in June 1999 (22), CGMS is increasingly used in the management of diabetes in children and adults, but there are few data regarding its use in neonates. Two main CGMS brands are in clinical use in neonates, namely the Medtronic Minimed (Northridge, CA, USA) and the Dexcom (San Diego, CA, USA), both providing real-time and retrospective modes. Neonatal studies have predominantly used Medtronic Minimed devices (13, 23-25), although a recent study used the Dexcom device (10). Tiberi et al. (24) compared data collected from the Medtronic Minimed CGMS devices with data obtained using a glucometer in preterm infants of the median gestational age of 32 weeks (range, 27–36 weeks) at increased risk of neonatal dysglycemia. Their Bland-Altman analysis for all glucose measurements showed that the mean difference (95% CI) was −6.8 (−37.4 to 23.8) mg/dL, indicating that the instrument showed a slight tendency to underestimate blood glucose value with wide variability. They concluded that CGMS was a safe and clinically adequate method for estimating glucose levels in preterm infants. Furthermore, it could be useful to reduce the number of heel sticks, observe glycemic trends, and promptly detect both

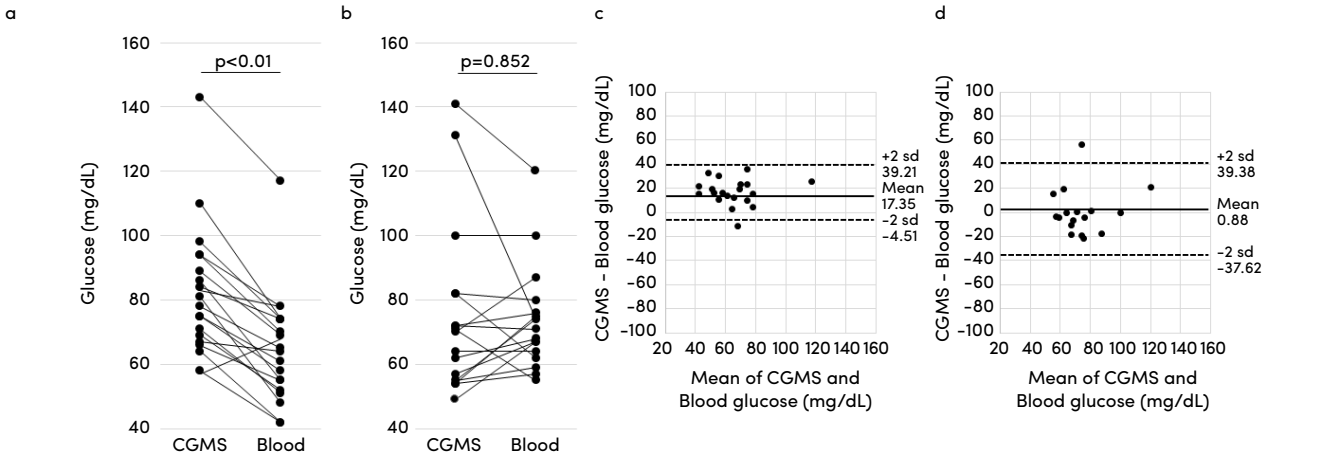

Figure 4. a-d. (a and b) Differences between CGMS and blood glucose values in each pair of measurements. Data were obtained (a) within (n=20 pairs) and (b) from (n=17 pairs) 3 hours after CGMS placement. (c and d) Bland-Altman plot. CGMS versus blood glucose values. The straight line shows the mean difference between CGMS and blood glucose values, and the two dotted lines show ±2 standard deviations. Data were obtained (c) within (n=20 pairs) and (d) from (n=17 pairs) 3 hours after CGMS placement
CGMS, continuous glucose monitoring systems

hypo and hyperglycemia In our study, the mean difference (±2 SD) between CGMS values and blood glucose concentrations was 9.78 (−24.68 to 44.25) mg/dL, indicating that factory-calibrated CGMS values showed a tendency to overestimate the blood glucose concentrations in term and near-term infants at risk of hypoglycemia soon after birth. Because it is important for medical staff in perinatal centers to identify hypoglycemia in neonates rather than hyperglycemia, this CGMS could not be used as an alternative to conventional glucose monitoring with painful heel stick blood sampling. However, although factory-calibrated CGMS has a tendency to overestimate blood glucose concentrations, it could be used to observe glycemic trends and promptly detect episodes of hypoglycemia.

Recently, two randomized controlled studies were performed to compare glucose levels monitored by real-time CGMS with those by intermittent capillary glucose testing in very preterm infants, which concluded that real-time CGMS played a beneficial role in managing hypoglycemia by matching the carbohydrate supply to the individual needs, reducing the continuance of hypoglycemia, increasing the time spent in the euglycemic range, and minimizing glycemic variability in preterm infants within the first week of life (10, 25). However, in our study, the number of data acquisitions per patient was not enough (median: 1.5, IQR: 1–2) to determine whether factory-calibrated CGMS could be used for glycemic trends.

Therefore, a randomized controlled trial will be needed to assess whether glucose administration guided by factory-calibrated CGMS is more effective than the standard-of-care blood glucose monitoring in maintaining euglycemia in term and near-term infants at risk of hypoglycemia (26). Thomson et al. (27) suggested that CGMS had sufficient accuracy and utility in preterm infants in their pilot studies to warrant formal testing in a randomized controlled trial.

In our study, factory-calibrated CGMS overestimated the blood glucose concentrations in patients within 3 hours after sensor insertion (mean difference [±2 SD] 17.35 [−4.54 to 39.21]) (Figures 4a and 4c), whereas there were much smaller differences in values measured by CGMS and heel pricks from 3 hours after sensor insertion (mean difference [±2 SD] 0.88 [−37.62 to 39.38]) (Figures 4b and 4d). Hoss U and Budiman ES analyzed the 14-day stability of the sensor signal collected by factory-calibrated CGMS, FreeStyle Libre. A lower value on the first day, which is presumably related to the insertion procedure of the sensor and the associated trauma, was observed. From Day 2 to Day 14, the median sensor sensitivity remained constant, reflecting stable sensor chemistry and negligible interference from the foreign body response. Therefore, this CGMS should be used cautiously in neonates at risk of hypoglycemia soon after birth, especially within 3 hours after sensor placement, because of its higher values than blood glucose values.

The limitations of our study are as follows: 1) we used StatStrip, the point-of-care glucometer, instead of gold standard laboratory glucose analyzers to measure blood glucose reference values. In our perinatal center, StatStrip is routinely used for blood glucose measurement because of its tighter agreement and accuracy (28). 2) The sample size is small; however, the observational design of the study allowed us to specifically address the feasibility and accuracy of the CGMS. We compared the CGMS values provided by FreeStyle Libre System with blood glucose concentrations provided by a single bedside glucometer, in contrast to other studies that have used a different point-of-care devices and different kinds of samples (29). 3) The number of data acquisitions per patient is small. Our protocol did not allow us to continue to collect CGMS and blood glucose data after blood glucose concentrations were stabilized because an additional invasive procedure, such as blood sampling, to healthy neonates who no longer need blood glucose management was thought to be harmful and unethical.

In conclusion, the CGMS system with factory-calibrated sensors was a safe and feasible method for glucose monitoring with a relatively good correlation with blood glucose levels. However, it has a tendency to overestimate the blood glucose concentrations. Therefore, this system should be used cautiously in neonates at risk of hypoglycemia, especially within 3 hours after sensor placement. A randomized controlled trial will be needed to assess whether the CGMS values could give a warning of alteration in trends of glucose monitoring.

Ethical Committee Approval: Ethical approval was obtained from the Ethics Committee of Saitama Medical Center, Saitama Medical University (approval number: 1864, approval date: 3/October/2019).

Informed Consent: Written informed consent was obtained from parents.

Authors Contributions: Concept – F.N.; Design – F.N.; Data Collection – E.N., S.O., J.O., K.T., T.M.; Data Analysis and Interpretation – E.N., S.O., K.K., F.N.; Writing – E.N., F.N.; Critical Review – E.N., F.N.; Final Approval – E.N., S.O., J.O., K.T., T.M., K.K., F.N.

Conflict of Interest: FreeStyle Libre System was leased from Abbott Japan Co., Ltd. (Tokyo, Japan).

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