ORIGINAL ARTICLE

Continuous Glucose Monitoring in 2013

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Introduction

CONTINUOUS GLUCOSE MONITORING (CGM) in the pediatric population with type 1 diabetes (T1D) was somewhat infamously described as “satisfaction without success” (1); success with CGM is strongly related to its use, and children and adolescents in some countries seem to be particularly reluctant to use CGM devices regularly as the behavioral changes these devices force on them may not be desirable. However, the SWITCH randomized clinical trial clearly demonstrated that CGM can be as successful in adolescents as in adults with T1D. Despite this fact, the reimbursement for CGM in Europe is still far from universal (2) but growing steadily as data on its benefits accumulate. The use of retrospective (professional) CGM has expanded far beyond its initial indications. Also, type 2 diabetes (T2D) is becoming an important focus for both retrospective and real-time CGM. Finally, an important study demonstrated that the home use of threshold insulin suspend based on sensor-augmented insulin pump therapy in T1D can reduce and prevent hypoglycemia.

Prognostic accuracy of continuous glucose monitoring in the prediction of diabetes mellitus in children with incidental hyperglycemia: receiver operating characteristic analysis

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Diabetes Technol Ther 2013; 15: 580–85

Aims

To evaluate the feasibility of CGM use in prediction of diabetes in children with incidental hyperglycemia (IH) and negative diabetes-related autoantibodies.

Methods

Thirty-one autoantibody-negative children with IH underwent a baseline assessment and were followed up for 23.8 months (range, 6–48 months). At the end of the follow-up, the receiver operating characteristic (ROC) areas under the curve (AUCs) of glucose data from 17 children who developed diabetes (group A; $n=17$) and 14 children who did not develop diabetes (group B; $n=14$) were compared.

Results

Two-hour glucose of oral glucose tolerance test (OGTT) was significantly associated with the development of diabetes (0.813; 95% confidence interval [CI] 0.621–0.954; glucose at 2 hours: 135 mg/dL [108–141] vs. 83.5 mg/dL [74.5–109.7] group A vs. group B, $p<0.01$) as was the AUC of glucose at OGTT (0.832; 95% CI 0.611–0.950). CGM glucose peak (0.803; 95% CI 0.621–0.923; 160 mg/dL [139.5–178.5] vs. 135 mg/dL [120.5–144], group A vs. group B, $p<0.01$), percentage of CGM glucose measurements inside the range 70–125 mg/dL (0.866; 95% CI 0.695–0.961), and percentage of CGM measurements ≥ 126 mg/dL (0.889; 95% CI 0.724–0.973; 13% [9.5–37.5] vs. 3% [1–4.5], group A vs. group B, $p<0.01$) showed significant prognostic performance (ROC AUCs, $p<0.0001$). A 2-hour OGTT plasma glucose cut-off of 135 mg % provided sensitivity=35.3%, specificity=100%, positive predictive value (PPV)=100%, and negative predictive value (NPV)=44%. A CGM glucose cut-off >156 mg % and a CGM% above 126 mg/dL cut-off $>42\%$ provided sensitivity=64.7%, specificity=100%, PPV=100%, and NPV=70%. The combination of CGM markers with each other or with the OGTT markers yielded higher ROC AUCs (ranging from 0.828 to 0.945). Interestingly, fasting blood glucose (FBG) and basal and glucagon-stimulated c-peptide were not different between the two groups. HbA1c was within the normal range in both groups.

Conclusions

CGM can be used for predicting the development of diabetes in children with IH and negative diabetes-related autoantibodies.

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Comment

This retrospective study on a limited group of children with IH (3) is interesting although it can only be considered as a pilot. HLA risk alleles are not determined, intravenous glucose tolerance test is not performed, and follow-up of diabetes-related antibodies is suboptimal. However, IH is a common finding in pediatrics, and less invasive and less costly investigations like CGM would certainly be of considerable benefit. Therefore, the use of CGM could be included in some large ongoing follow-up and intervention studies in pediatric populations at risk for developing T1D, where a more robust calculation of its predictive value would be possible.

Susceptibility of interstitial continuous glucose monitor performance to sleeping position

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J Diabetes Sci Technol 2013; 7: 863–70

Aims

To evaluate the impact of different sleeping positions on the performance of CGM sensors in T1D.

Methods

Healthy volunteers were inserted with commercially available sensors for 4 days in the abdominal subcutaneous tissue (four sensors per person, two per side). Sleep was video-recorded and nocturnal sleeping position determined from recordings. Sleeping positions were correlated to CGM sensor readings.

Results

The median glucose concentration of the four sensor readings was characteristically 70–110 mg/dL during sleep. Individual sensors intermittently recorded irregular glucose readings (>25 mg/dL away from median) that were strongly correlated with sleeping positions where subjects were lying on the sensors. Most of these irregular sleep-position-related CGM readings were abrupt decreases in reported glucose values, supposedly because of local blood and/or interstitial fluid flow disturbances caused by tissue compression. Rarely, abrupt elevations in CGM glucose readings were observed.

Conclusions

Interstitial fluid and local blood flow disturbances may be associated with sleep-position-related abrupt decreases in CGM-recorded glucose values.

Comment

This study (4) confirms several anecdotal reports of nocturnal sleep-position-related abrupt decreases in CGM sensor glucose values. Factitious hypoglycemia caused by pressure on the sensor insertion site is

commonly reported by mothers regularly checking their babies during sleep. In order to increase the reliability of CGM devices, an algorithm that would detect pressure-induced factitious hypoglycemia during sleep would be of substantial importance and would bring direct clinical benefit. Factitious IH, also rarely observed in this study, has currently no clear physiological explanation. The detection of factitious IH is of particular importance for closed-loop insulin delivery systems, as more insulin is erroneously delivered to the patient possibly resulting in severe hypoglycemia.

The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: a randomized controlled trial

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Diabetologia 2012; 55: 3155–62

Aims

To evaluate the efficacy of adding CGM to existing continuous subcutaneous insulin infusion (CSII) therapy without the impact of diabetes-related education and patient-care-giver contact time in T1D.

Methods

To control for known confounding factors, a randomized crossover design was used. Children (6–18 years) and adults (19–70 years) on CSII with HbA1c between 7.5% and 9.5% were separately electronically randomized to either a Sensor-On or Sensor-Off arm for 6 months. Participants were crossed over to the other arm for 6 months after a 4-month washout period. The primary outcome was the difference in HbA1c levels between arms after 6 months. Secondary endpoints were mean 24-hour glucose and 24-hour AUC values, and changes in the time spent in hypoglycemia <70 mg/dL (<3.9 mmol/L), IH >180 mg/dL (>10 mmol/L), and euglycemia 70–180 mg/dL (3.9–10 mmol/L).

Results

A total of 185 individuals were screened and 153 (52% male) randomized after the run-in period. The overall mean HbA1c level was 8.04 in the Sensor-On arm and 8.47% in the Sensor-Off arm after 6 months (difference –0.43%; 95% CI –0.32%, –0.55%; $p < 0.001$). The mean difference in children and adolescents was –0.46% (95% CI –0.26%, –0.66%;

$p < 0.001$) and -0.41% (95% CI -0.28% , -0.53% ; $p < 0.001$) in adults. Mean overall sensor use was 80% (median 84%) of the required time (mean 81% over the final 4 weeks); in the pediatric group it was 73% (median 78%) (mean 74% over the final 4 weeks); in the adult group it was 86% (median 89%) of the required time (mean 87% over the final 4 weeks). Time spent < 70 mg/dL (< 3.9 mmol/L) was significantly shorter during the Sensor-On period compared with the Sensor-Off period (19 vs. 31 min/day, respectively; $p = 0.009$). Glycemic variability assessed by 24-hour standard deviation (SD) of glucose concentration was also significantly lower in the Sensor-On arm. The number of daily boluses, temporary basal rates, and manual insulin suspends was significantly higher in the Sensor-On arm. Four severe hypoglycemic events occurred in the Sensor-On arm vs. two in the Sensor-Off arm ($p = 0.40$).

Conclusions

The addition of CGM to CSII therapy resulted in an improvement in HbA1c with a concomitant decrease in time spent in hypoglycemia in both pediatric and adult participants with T1D. More frequent self-adjustments of insulin therapy were observed in the intervention arm.

Comment

The SWITCH study (5) provides a unique evidence of CGM efficacy because of its crossover design eliminating the most common confounding factors of this treatment modality: the amount of diabetes-related education and patient-caregiver contact. Contrary to the Juvenile Diabetes Research Foundation (JDRF) sensor study (6), the significant reduction in HbA1c is similar in children and adolescents as compared to adults, with a high sensor use also at the end of the study. Moreover, the significant reduction in HbA1c is accompanied with a reduction of time spent in hypoglycemia, corroborating the results of a previous study on a well-controlled population of adolescents and adults with T1D (7). Interestingly, the use of the sensor was accompanied with significantly more active insulin dose adjustments, indicating a behavioral modification.

Heterogeneity of responses to real-time continuous glucose monitoring (RT-CGM) in patients with type 2 diabetes and its implications for application

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Diabetes Care 2013; 36: 786–92

Aims

To characterize glucose response patterns of people who wore a real-time continuous glucose monitor (RT-CGM) as an intervention to improve glycemic control. Participants had T2D, were not taking prandial insulin, and interpreted the RT-CGM data independently.

Methods

Data were from the first 12 weeks of a 52-week, prospective, randomized trial comparing RT-CGM ($n = 50$) with self-monitoring of blood glucose ($n = 50$). RT-CGM was used in 8 of the first 12 weeks. HbA1c was collected at baseline and quarterly. This analysis included 45 participants who wore the RT-CGM for ≥ 4 weeks. Analyses examined the RT-CGM data for common response patterns using a novel approach. It then used multilevel models for longitudinal data, regression, and nonparametric methods to compare the patterns of A1C, mean glucose, glycemic variability, and views per day of the RT-CGM device.

Results

There were five patterns identified. For four patterns, mean glucose was lower than expected as of the first RT-CGM cycle of use given participants' baseline HbA1c. They were named favorable responses but with high and variable glucose ($n = 7$); tight control ($n = 14$); worsening glycemia ($n = 6$); and incremental improvement ($n = 11$). The fifth had no response ($n = 7$). A1C, mean glucose, glycemic variability, and views per day differed across patterns at baseline and longitudinally.

Conclusions

The patterns identified suggest that targeting people with higher starting HbA1cs, using RT-CGM short term (e.g., 2 weeks) and monitoring for worsening glycemia that might be the result of burnout, may be the best approach to using RT-CGM in people with T2D not taking prandial insulin.

Comment

The use of RT-CGM in T2D patients not taking prandial insulin has shown to be effective in improving glycemic control as measured by HbA1c in the majority of subjects (8). Specific behaviors that led to improvement in glycemic control were not measured in this study, but patients who looked at the RT-CGM tracings frequently clearly improved their glycemic control. Targeting people with higher A1Cs as well as using the device in short-term periods and monitoring for worsening glycemic control while wearing RT-CGM may improve outcomes using RT-CGM in this population.

Influence of glycemic variability on HbA1c level in elderly male patients with type 2 diabetes

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Intern Med 2012; 51: 3109–13

Aims

To investigate the influence of glycemic variability on the HbA1c level in elderly male patients with T2D.

Methods

The 24-hour glucose profiles were obtained using a CGM system in 291 elderly male patients with T2D who were

hospitalized. The relationship between the glycemic variability and HbA1c level was assessed in these patients.

Results

The mean amplitude of glycemic excursions (MAGE) in patients with HbA1c $\geq 7.0\%$ was significantly higher than that in patients with HbA1c $< 7.0\%$ (4.33 ± 1.67 vs. 3.48 ± 1.46 mmol/L, $p < 0.001$). A simple (Pearson's) correlation analysis indicated that the MAGE was significantly correlated with the HbA1c ($r = 0.229$, $p < 0.001$). Compared with the lowest quartile, the highest quartile of the MAGE was associated with a significantly increased risk of having a HbA1c $\geq 7.0\%$ after multiple adjustments ($p < 0.001$).

Conclusions

The glycemic variability had a significant influence on the HbA1c level in elderly male patients with T2DM. The present data suggest that patients with higher glycemic variability might have higher HbA1c levels.

Comment

Prior studies have shown that mean glucose but not glycemic variability had a significant influence on HbA1c levels. Most of these studies had not used CGM to measure glycemic variability. In this inpatient cohort of 291 elderly males, MAGE as determined by CGM correlated with HbA1c levels where plasma glucose and other clinical factors did not correlate with HbA1c levels (9). Future studies using CGM to determine MAGE are needed to verify this finding.

Continuous glucose monitoring and cognitive performance in type 2 diabetes

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Diabetes Technol Ther 2012; **14**: 1126–33

Aims

T2D is associated with reductions in cognitive function that are associated with HbA1c levels, but there is no information on whether cognition is related to postmeal glucose spikes. The authors explored the relationship of cognition to glucose levels measured by a CGM system (CGMS) both before and after a weight-loss diet.

Methods

Forty-four subjects with T2D (59.0 ± 6.2 years old; body mass index, $32.8 - 4.2$ kg/m²; HbA1c, $6.9 \pm 1.0\%$) completed an 8-week energy-restricted (approximately 6–7 MJ, 30% deficit) diet. Cognitive functioning (short-term memory, working

memory, speed of processing [inspection time], psychomotor speed, and executive function) was assessed during four practice sessions, baseline, and week 8. Parallel glucose levels were attained using the CGMS in 27 subjects. Outcomes were assessed by FBG, postprandial peak glucose ($G_{\max}$), time spent > 12 mmol/L ($T > 12$), and 24-hour area under the glucose curve (AUC24).

Results

Despite a fall in FBG of 0.65 mmol/L after 8 weeks, digits backward results correlated with FBG at both week 0 and week 8 ($r = -0.43$, $p < 0.01$ and $r = -0.32$, $p < 0.01$, respectively). Digits forward results correlated with FBG ($r = -0.39$, $p < 0.01$), $G_{\max}$ ($r = -0.46$, $p < 0.05$), and AUC24 ($r = -0.50$, $p < 0.01$) at week 0 and FBG ($r = -0.59$, $p < 0.001$), $G_{\max}$ ($r = 0.37$, $p = 0.01$), AUC24 ($r = -0.41$, $p < 0.01$), and percentage weight loss ($r = 0.31$, $p < 0.01$) at week 8. Cognitive function was not altered by weight loss, gender, baseline lipid levels, or premorbid intelligence levels (National Adult Reading Test).

Conclusions

FBG, $G_{\max}$, and AUC24 were related to cognitive function, and an energy-restricted diet for 8 weeks did not alter this relationship.

Comment

This small study (10) of relatively well-controlled 44 type 2 DM subjects showed that FBG, postprandial peak glucose, and total glucose exposure correlated with cognitive function, but intervention with a weight loss diet did not affect cognitive function in spite an improvement in glycemic control and other glycemic parameters measured by CGM. These results corroborate previous findings in a cohort of elderly patients with T2D (11). Limitations of this study were that these patients were well controlled with a mean A1C of 6.8%. Future research should look at an intervention in a poorly controlled group of type 2 patients to see if they may show an improvement in cognitive function.

Relationship between fluctuations in glucose levels measured by continuous glucose monitoring and vascular endothelial dysfunction in type 2 diabetes mellitus

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Cardiovasc Diabetol 2013; **12**: 1

Aims

Fluctuations in blood glucose levels cause endothelial dysfunction and play a critical role in onset and/or progression of atherosclerosis. This group hypothesized that fluctuation in blood glucose levels correlate with vascular endothelial dysfunction and that this relationship can be assessed using CGM.

Methods

Fluctuations in blood glucose levels were measured over 24 hours by masked CGM on admission day 2 in 57 patients with T2D. The reactive hyperemia index (RHI), an index of vascular endothelial function, was measured using peripheral arterial tonometry (EndoPAT) on admission day 3.

Results

RHI correlated with SD ($r = -0.504$; $p < 0.001$), the MAGE ($r = -0.571$; $p < 0.001$), mean postprandial glucose excursion ($r = -0.411$; $p = 0.001$), and percentage of time ≥ 200 mg/dL ($r = -0.292$; $p = 0.028$). In 12 patients with hypoglycemia, RHI also correlated with the percentage of time at hypoglycemia ($r = -0.589$; $p = 0.044$). RHI did not correlate with HbA1c or fasting plasma glucose levels. Furthermore, RHI did not correlate with low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglyceride levels or with systolic and diastolic blood pressures. Finally, multivariate analysis identified MAGE as the only significant determinant of RHI.

Conclusion

Fluctuations in blood glucose levels play a significant role in vascular endothelial dysfunction in T2D.

Comment

Fluctuations in blood glucose levels measured by CGM, specifically MAGE, correlate to vascular endothelial dysfunction in T2D (12). No measures of oxidative stress were measured in this study; thus, the direct cause of this vascular endothelial dysfunction by variability of glucose was not determined. However, glucose variability influences endothelial function even in nondiabetic subjects (13). Further prospective studies on prevention and minimization of variability of glucose are needed to see if such intervention can lower markers of oxidative stress and future cardiovascular events.

Threshold-based insulin-pump interruption for reduction of hypoglycemia

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N Engl J Med 2013; **369**: 224–32

Aims

To evaluate sensor-augmented insulin-pump therapy with and without the threshold-suspend function in T1D patients with nocturnal hypoglycemia.

Methods

Patients aged 16–70 years with T1D for >2 years, HbA1c of 5.8–10.0%, and on insulin-pump therapy for more than 6 months were recruited. Those with more than one episode of severe hypoglycemia (resulting in coma or seizures or requiring medical assistance) were excluded. Patients who wore sensors $>80\%$ of the time and had at least two nocturnal hypoglycemic events during the 2 weeks run-in phase were eligible for randomization to receive either sensor-augmented insulin-pump therapy with the threshold-suspend feature (threshold-suspend group, threshold 70–90 ng/dL/3.9–5 mM/) or standard sensor-augmented insulin-pump therapy (control group) for 3 months. The primary efficacy end point was the AUC for nocturnal hypoglycemic events, and the primary safety end point was the change in HbA1c during the study.

Results

The mean ($\pm$ SD) AUC for nocturnal hypoglycemic events in the threshold suspend group was 37.5% less than that of the control group (980 ± 1200 mg/dL $\times$ min vs. 1568 ± 1995 mg/dL $\times$ min) ($p < 0.001$). HbA1c did not change significantly in either group, and the between-group difference was 0.05% (CI -0.05 to 0.15). The rate of nighttime hypoglycemic events was reduced by 31.8% (1.5 ± 1.0 vs. 2.2 ± 1.3 per patient-week, $p < 0.001$). The mean per-patient number of automatic nighttime pump suspensions was 0.77, with a median duration of 11.9 minutes (mean, 39.4); 43.1% lasted for less than 5 minutes; and 19.6% for 2 hours. A total of 111 of 121 patients group had at least one nocturnal threshold-suspend event lasting for 2 hours with the mean sensor glucose value at the end of it of 92.6 ± 40.7 mg/dL (5.1 ± 2.6 mM). No difference was observed in scores on the Hypoglycemia Fear Survey and the EQ-5D between groups. No severe hypoglycemic events occurred in the threshold-suspend group and 0.13 per patient-year in the control group. No diabetic ketoacidosis (DKA) was recorded.

Conclusion

The addition of automatic threshold pump suspension over a 3-month period can reduce the number and severity of hypoglycemic episodes at night without any apparent loss in overall glucose control.

Comment

The success of the threshold insulin suspend in the ASPIRE in-home study (14) has importance beyond its considerable formal achievements: a commercially available automated system connecting CGM with insulin delivery brought clinical benefit to patients during home use. Recently, a full closed-loop insulin delivery system, the MD-Logic artificial pancreas, lessened nocturnal hypoglycemia and improved metabolic parameters in the first randomized controlled trial in home settings (15). As automated actions of these systems do not need the involvement of the patients, the major barriers of diabetes-related technology—adherence and compliance—seem to be circumvented. It would therefore seem logical to pursue the path to a commercial artificial pancreas using subcutaneous glucose sensing and insulin delivery with maximal speed.

Conclusion

CGM is now an established treatment modality for diabetes with expanding indications, helping improve the well-being of patients and proficiency of their caregivers in various challenging situations, including sports and prolong fasting (16). CGM use in T2D seems to be particularly successful in both retrospective and real-time use. New technical improvements such as combined insulin set with a continuous sensor (17), enhancement of the alarm function at home (18), and improved sensor accuracy and performance (19) will also improve the acceptability of this treatment modality in all age groups. However, as psychosocial barriers vary between individual users (20), the use of CGM may finally be most efficient within a closed-loop system.

Author Disclosure Statement

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