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Diabetes Technology and Therapeutics
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Full Title: Baseline glucose variability and inter-week variability affects the time to stability of continuous glucose monitoring (CGM) derived glycemic indices

Running Title: "GV affects the time to stability of CGM indices"

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Abstract:

Objectives: To study the effect of baseline glucose variability (GV) on the time to stability and inter-week variability (IWV) of continuous glucose monitoring (CGM) derived glycemic indices.

Materials and methods: Anonymized CGM data (median duration 32 weeks, ≥ 70% data coverage) of 85 adults with type 1 diabetes; age (41 ± 12 years), 66.3% women, HbA1c (7.5 ± 1.2%, 58 mmol/mol) were analyzed. We evaluated the time to stability, i.e. the minimum duration of data that provided a close (r^2 ≥0.9) correlation with data taken across the whole sampling period and IWV. We also evaluated the impact of baseline variability on the time to stability.

Results: For the whole dataset, all indices achieved stability (r^2 ≥ 0.9) by 9 weeks (range 5-9). Time to stability progressively increased from the lowest quartile to the highest quartile of baseline CV. Time above range (TAR) and time below range (TBR) had higher IWV than Time in Range (TIR) (%CV_{IWV}: TIR-16%, TAR-31%, TBR-62%).

Conclusion: Baseline GV and IWV of indices affect the time to stability of glycemic indices. We recommend a minimum of 9 weeks of data to represent long term CGM data.

Keywords: Continuous glucose monitoring, glucose variability, type 1 diabetes, time in range, coefficient of variation.

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Introduction:

Continuous glucose monitoring (CGM) is increasingly used for the care of type 1 diabetes worldwide.[1] Recent data of people with type 1 diabetes from Europe show that a third are using CGM or flash glucose monitoring, and terms such as time in range (TIR), glucose variability (GV) and time in hypoglycemia are entering the clinical lexicon.[2,3] CGM is a powerful tool that provides a ready assessment of glucose fluctuations, that often infer a mismatch between insulin requirements and insulin delivery at any given time.

It is, however, a common clinical experience that CGM profiles demonstrate not only within-day variability but also vary between days and can often be very different between weeks. In this scenario, given the frequent use of CGM derived measures like TIR, Time below Range (TBR), Time above range (TAR), and coefficient of variation (CV) for both clinical and academic purposes[3–5], it is very important to assess the minimum CGM duration that provides a stable representation of an individual's glycemic signature; 'time to stability'.

A previous analysis of shorter duration CGM data from clinical trials suggested that two weeks of data provided a reasonable (r = 0.7) correlation with the overall glycemic picture.[6] However, with the availability of longer duration of CGM data, and many people with type 1 diabetes using CGM uninterrupted, we felt the need to re-assess this relationship. We aimed to study the relationship between CGM derived glycemic indices from incremental (1 week) sampling durations to long-duration CGM data. We hypothesized that baseline glucose variability (GV) may have an impact on the time to stability of glycemic indices.

Material and Methods

We obtained anonymized CGM data from people with type 1 diabetes attending the diabetes clinic at King's College Hospital, London. We included people with T1D and a CGM duration of ≥ 6 weeks with >70% data coverage for the duration of wear and excluded children (age <18 years). There were no other exclusion criteria for representativeness of the sample.

We calculated TIR (3.9-10mmol/L), TAR (>10mmol/L & >13.9mmol/L), TBR (<3.9mmol/L & <3mmol/L), mean glucose, %CV, standard deviation (SD), Inter-quartile Range (IQR), Mean amplitude of glycemic excursion (MAGE) and continuous overall net glycemic action

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(CONGA1). CONGA1 and MAGE were calculated using the EasyGV ver 9.0R2[7]. These variables were calculated for the entire duration of CGM data available and for incremental 1-week duration from the start of available data. We then analyzed the time to stability for each variable, defined as the minimum duration of data giving a coefficient of determination, r^2, ≥0.90, to the whole CGM data. We also stratified the cohort based on quartiles of week-1 %CV. We calculated the inter-week variability (IWV) of each CGM index as the coefficient of variation ($\%CV_{IWV}$). Microsoft Excel (Office 365) and SPSS version 25 were used for data extraction, reorganization and statistical analysis.

Results

85 people with type 1 diabetes met the inclusion criteria (52 using freestyle libre and 33 using Dexcom G5/6). Age (41 ± 12 years), 66.3% women, HbA1c (7.5 ± 1.2%, 58 mmol/mol). The median duration of CGM data was 32 weeks (interquartile range: 18-43 weeks). 52 (61%) had continuous data for ≥ 24 weeks.

Effect of incremental sampling duration

The correlation between glycemic indices derived from incremental durations of sampling and the whole CGM data increased with longer durations of sampling. (Figure 1 & Figure 2) The time to stability in weeks were 6 for mean glucose, SD, TIR, and TAR>10, MAGE and IQR; 7 for %CV and TAR>13.9, 5 for TBR <3 and CONGA1 and 9 for TBR <3.9. However, the monthly mean value for each of these indices for the whole group did not change significantly from month 1 to month 6 (Supplementary Table S1).

Effect of baseline glucose variability

We divided the cohort into four quartiles based on week-1 %CV (%CV: Q1, <33.7; Q2, 33.7 - <37.6; Q3, 37.6 - <42.2 and Q4, 42.2 - <61.3). The time to stability increased from the lowest (Q1) to the highest quartile (Q4) for mean glucose, TIR, and TAR>10, TAR>13.9. (Figure 3) However, for TBR<3.9 and TBR<3 such an effect of baseline GV was not evident. For TBR<3.9 Q1, Q2 and Q4 had a shorter time to stability than Q3. This effect of baseline GV on the time to stability of glycemic indices was consistent even when only the 52 people with CGM duration of ≥24 weeks were analyzed. The time to stability (weeks) for

Q1 to Q4 varied from 2 to 16 for mean glucose, 3 to 21 for TIR, 3 to 16 for TAR>10, 1 to 30 for TAR>13.9, 6 to 16 for TBR <3.9 and 5 to 16 for TBR<3.

Inter-week variability (IWV) of glycemic indices

Inter-week variability (IWV) was assessed as $\%CV_{IWV}$. The mean $\%CV_{IWV}$ was 9% for mean glucose, 13% for SD, 11% for %CV and 16% for TIR. It was 31% for TAR>10 and 64% for TAR>13.9. TBR<3.9 had a $\%CV_{IWV}$ of 62% while TBR<3 had the highest IWV at 108%. (Figure 4) Indices measuring glycemia beyond the normal range (TAR & TBR) had higher IWV.

Clinical examples

To illustrate the findings above we present the variation in 1 & 2 week and 1 & 3-month data of two participants (L1 and L35), both on insulin pump therapy with similar HbA1c of 7.8 and 7.9% respectively at week 1. L1 had a baseline CV of 33.5% (Q1), and L35 had a week 1 CV of 48.2% (Q4). L1 with low baseline glycemic variability had smaller variations of glycemic measures across the sampling intervals; mean glucose (8.6 to 9.2mmol/L), TBR (2.0-4.9%), TIR (63.6 - 69.3%) and TAR (26.3 - 32.8%). In contrast, L35 with a higher baseline glucose variability, while having smaller variations in mean glucose (8.4 to 9.2 mmol/L) and TIR (46.0 to 54.6%), had large variations in TBR (9.1 - 13.4%) and TAR (31.1 - 44.2%).

Discussion

We found that the CGM derived glycemic indices we analyzed took between 5 to 9 weeks to stabilize and provide a high degree of correlation with long-duration data. Baseline GV affects the time to stability of various glycemic indices. We defined “time to stability” as the minimum duration of time (data) needed to represent the glycemic signature of a person with diabetes. A higher baseline glucose variability increases the time to stability for CGM derived indices. While previous studies concluded that 12-14 days of data was optimal for a 3 month period [6,8,9], the same does not apply for longer durations of CGM data. A minimum sampling duration of 9 weeks (range 5-9 weeks) is required for the

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commonly used CGM indices when analyzing long-duration CGM data of more than 6 months. These findings are of relevance both in the clinical and research settings.

Glycemia is affected by both diabetes regimen setup and behavioral factors. The regimen setup, what we call "structural" factors are the balance between basal and bolus insulin, the insulin to carbohydrate ratio (ICR) or insulin sensitivity factor (ISF) used to determine the doses of rapid-acting insulin. "Behavioral" factors are events like a missed meal bolus, the frequency of glucose measurements, timing of rapid-acting insulin related to meals and over or under-correction of high or low readings. Dysglycemia related to behavioral factors, like hyperglycemia from a missed bolus or cannula failure and hypoglycemia related to alcohol or exercise is likely to result in short-term glycemic variability. On the other hand, inappropriate structural set up of the insulin regimen, like a wrong basal-bolus split, ICR or ISF are likely to result in recurrent long-term dysglycemic patterns. Although HbA1c remains an important measure of glycemia, changes to the treatment regimen are often triggered by CGM derived indices like the TIR, TBR, TAR, SD and %CV and these indices are being incorporated into the routine clinical conversation in diabetes clinics across the world. When reviewing CGM data, most health care professionals opt to use the pre-set duration, usually one to four weeks, to generate the above indices. A review of the recent few weeks of CGM provides an excellent opportunity to discuss the impact of self-care behaviors on glycemia, as people tend to remember recent events better. However, our data shows that a longer duration of data, possibly up to 9 weeks, is required for a true representation of the glycemic profile and assess longer-term risks of hyper- or hypo-glycemia or the impact of "structural" changes to the insulin regimen like changes to the ICR or ISF. This becomes extremely important when clinical decisions such as initiation or withdrawal of a diabetes-related-technology are based on these CGM indices as thresholds.

These findings are equally important in a research setting as CGM derived indices are gaining popularity as outcome measures.[4] Firstly, the baseline glucose variability of the study population of interest must be considered. Populations with a high baseline GV (e.g., diabetes on intermittent dialysis[10], diabetes with eating disorders) will have a longer time to stability for CGM indices.[11] This duration will be shorter in populations with a low

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baseline GV (e.g.: type 1 diabetes in the honeymoon phase, early type 2 diabetes[12], type 1 on closed-loop systems[13]). Secondly, the CGM index of interest must be considered. CGM indices measuring the extremes of glycemia like the TBR and TAR have a higher IWV than TIR. Hence while designing studies with CGM derived indices as outcome measures, the baseline GV of the population and the inherent IWV of the CGM index must be considered.

While our data shows that baseline glycemic variability influenced the time to stability other potential confounders for this effect need to be considered. An improvement in glycemia over time to reach a new steady state was considered, by comparing the monthly mean of these glycemic indices over six months and no significant change over time was found.

The limitations of this study include a non-random sample selection and the lack of analysis of the indications for CGM initiation. Further, we did not analyze all the glycemic indices that have been described in the literature. Another factor that affects this correlational analysis is the inherent heterogeneity of glycemia in the type 1 diabetes population and variability due to sampling. Ours is a non-random opportunistic sample of people with type 1 diabetes using CGM, hence, the findings may not be generalized to all people with type 1 diabetes. However, we believe that our real-life data set may be more representative of a broader "real-world population" of people with type 1 diabetes using CGM than data from clinical studies that often have restrictive inclusion and exclusion criteria.

Conclusion

This study adds a novel perspective to the analysis of minimum time to stability for CGM indices with implications for the use of CGM in both the clinical and research settings. Whilst the use of short duration CGM data (e.g. 2 weeks) in clinical consultations have great educational value in discussing the diabetes self-care behavior, longer duration data which provides the bigger picture should be used to make treatment decisions related to the structural setup of the insulin replacement regimen. The baseline glucose variability of the person/population and the CGM index of interest impacts the minimum time to stability of a CGM index derived from long-duration CGM data.

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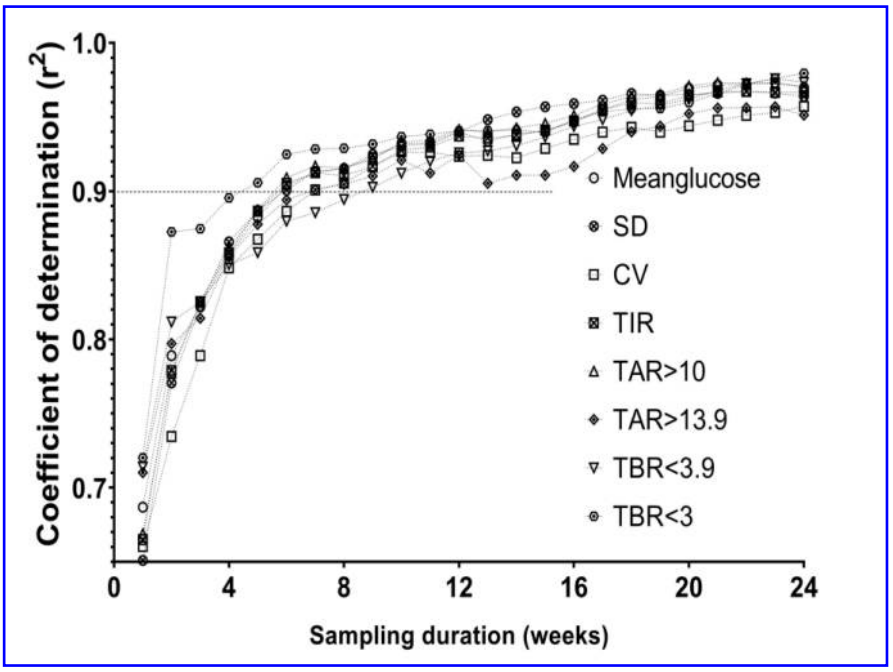

Figure 1: Correlation between glycemic indices derived from incremental sampling durations and the whole CGM data.

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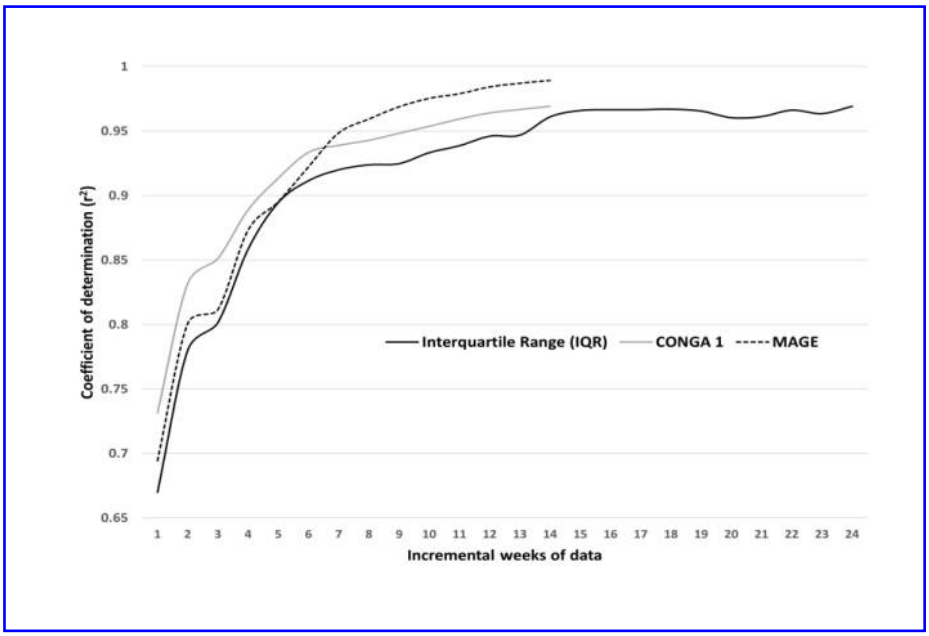

Figure 2: Correlation between Interquartile range (IQR), Mean amplitude of glycemic excursion (MAGE), and Continuous Onset Net Glycemic Action (CONGA1) derived from incremental weekly data to whole CGM data. (Data for MAGE and CONGA1 are limited to 14 weeks due to the limits of analysis on EasyGV ver9.0R2)

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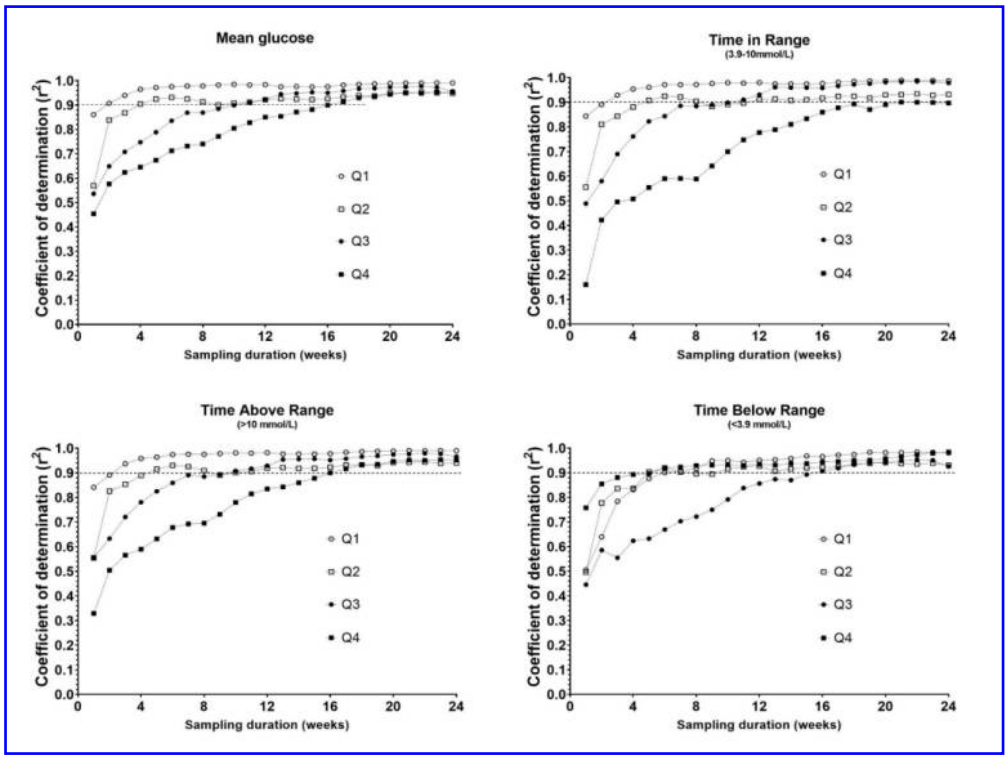

Figure 3: Effect of baseline glucose variability (week 1 %CV) on the correlation between glycemic indices derived from incremental sampling durations to the whole CGM data. (%CV: Q1, <33.7; Q2, 33.7 to <37.6; Q3,37.6 to <42.2 and Q4, 42.2 to <61.3)

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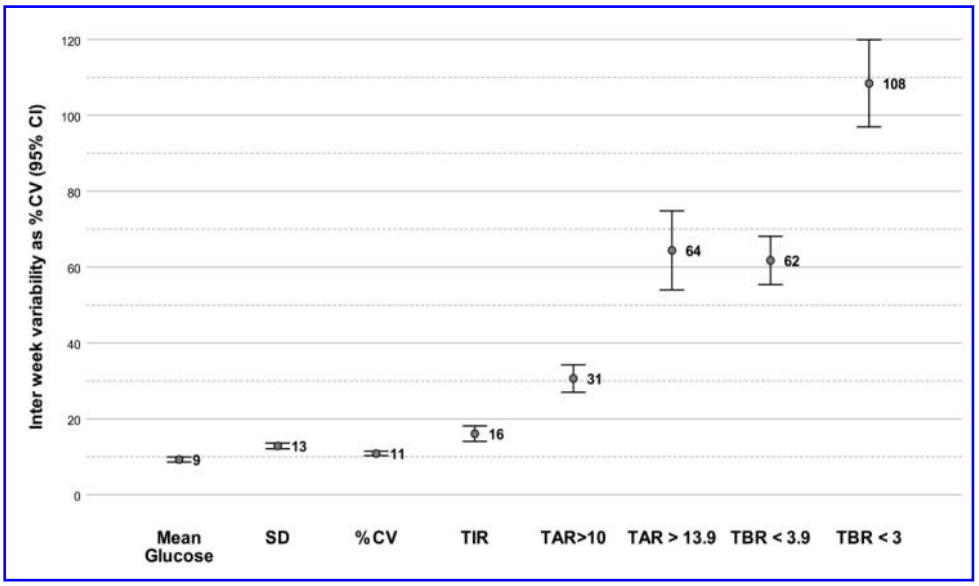

Figure 4: Inter-week variability of CGM derived glycemic indices expressed as %CV

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Supplementary Table S1: Comparison of average value of glycemic indices for each month for the whole cohort						
	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Mean glucose (mmol/L)	8.68	8.83	8.96	8.90	8.85	8.96
SD (mmol/L)	3.39	3.41	3.46	3.46	3.44	3.54
CV (%)	37.40	38.24	37.86	36.95	38.68	37.55
TIR (%)	60.19	59.83	59.70	59.26	59.54	58.64
TAR>10(%)	31.98	32.87	34.13	34.91	34.09	35.08
TAR>13.9(%)	8.43	9.33	9.21	8.81	8.61	9.46
TBR<3.9(%)	4.55	4.05	4.13	3.79	4.02	4.06
TBR<3(%)	.69	.76	.89	.69	.71	.75

No statistically significant differences between the months were found.