



Real-World Continuous Glucose Monitoring Profiles in Individuals with Prediabetes

Authors: Kevin Miller¹, Eden Miller¹, Benecia Jude Jose, BA², Naunihal Virdi, MD, FACP², Tim Dunn PhD²

Affiliations:

¹Diabetes and Obesity, Bend OR, USA

²Abbott Diabetes Care, Alameda, CA USA

Background

- CGM can potentially differentiate glycemic patterns between individuals with prediabetes and normoglycemia¹.
- Time in tight range may be more informative than time in range when evaluating glycemic control at lower average glucose levels².
- The updated Glucose Management Indicator (*uGMI*) shows improved alignment with laboratory A1C compared to GMI, particularly at lower A1C levels³.

Collectively, these findings suggest that CGM metrics in individuals with prediabetes are sensitive to progressive changes in glycemic regulation.

Study Objective:

Summarize real-world CGM glucose data from individuals with prediabetes using FreeStyle Libre (FSL) systems 1 or 2, stratified by glycemic control as described by updated Glucose Management Indicator (*uGMI*).

Methods

Study design:

In this retrospective, real-world study, we analyzed linked database of two de-identified data sources:

- LibreView: longitudinal continuous glucose values of FSL users in the United States
- Inovalon Insights: closed administrative health insurance claims in the United States

Records were linked using Datavant's de-identification and linking technology for structured data.⁴ The linked database is certified via expert determination as required under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The expert determination was performed by Datavant Privacy Hub, where an expert statistician certified that enough identifying data elements have been removed from LibreView and Inovalon Insights that there is a "very small risk" that a recipient or data analyst could identify an individual.

Inclusion criteria:

- Prediabetes diagnosis: identified using ICD-10-CM R73.x claims and required continuous medical and pharmacy enrollment. only had prediabetes across their full claims' history or eventually progress to type 2 diabetes.
- FSL was used during prediabetes and the sensor had data sufficiency; at least 5 days of sensor wear over 14-day period and 20 of the 24 hours of the day have at least 10 readings spread across at least 5 calendar dates
- Had a *uGMI* % of greater than 5.0 and less than 7.0

Exclusion criteria:

- Had history of type 1/type2/gestational prior to prediabetes diagnosis
- Had a gestational or Type 1 diagnosis after prediabetes diagnosis

Figure 1. Study design



Table 1. Demographics

Race	n	Gender	n
Black or African American	99	Female	1826
Hispanic or Latino	236	Male	1220
White	1149		
Some Other Race	1826		
Asian or Pacific Islander	211		
Unknown	1236		

- Total of 3,046 participants were included (mean age 48.7 years).
- 443 were seen progressing to type 2 diabetes, while 2,603 had only prediabetes related claims.

Analysis

GMI is calculated by an empirical known formula employing average glucose (AG) levels, while the *uGMI* formula accounts for population-based red blood cell factors³. Thus, *uGMI* strata was used a proxy for levels of glucose management as *uGMI* shows improved alignment with laboratory A1C compared to GMI³.

$$uGMI(\%) = (15.36/AG \text{ (mg/dL)} + 0.0425)^{-1}$$

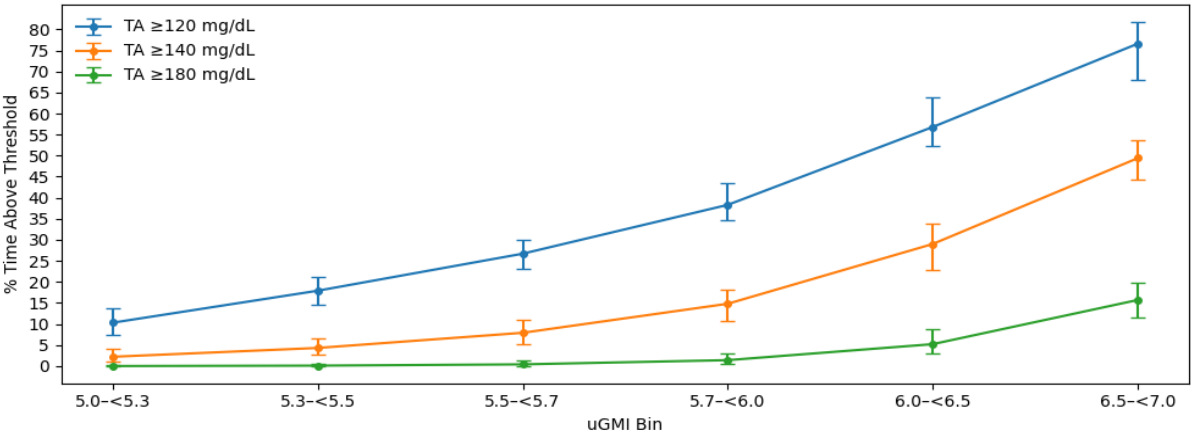
- CGM-derived glucose metrics were summarized across predefined *uGMI* strata.
- Metrics including mean glucose, time above thresholds (TA120, TA140, TA180), and glucose variability (CV) were summarized using medians and interquartile ranges (IQR).

Results

Table 2. *uGMI* Strata

<i>uGMI</i> %	n	<i>uGMI</i> Mean %	Mean Glucose mg/dL Median (IQR)	CV Glucose Median (IQR)
5.0 to <5.3	1061	5.1	101 (99, 103)	15.1 (12.7, 18.1)
5.3 to <5.5	622	5.4	108 (106, 109)	15.3 (13.0, 18.2)
5.5 to <5.7	469	5.6	113 (111, 114)	16.5 (13.7, 19.5)
5.7 to <6.0	371	5.8	119 (117, 121)	18.0 (14.9, 21.7)
6.0 to <6.5	307	6.2	130 (127, 133)	20.4 (17.4, 25.0)
6.5 to <7.0	216	6.8	146 (142, 149)	23.5 (19.7, 28.7)

uGMI: updated GMI. CV: coefficient of variation. IQR: Interquartile range



%TA120: %time glucose was above 120 mg/dL. %TA140: %time glucose was above 140 mg/dL. %TA180: %time glucose was above 180 mg/dL. Values are presented as medians with interquartile ranges (IQRs). Lines connect medians across ordered *uGMI* strata for visualization of trends.

Conclusion

Time above 120 and 140 were more sensitive than TA180 to forecast those patients who had progressed to prediabetes (*uGMI* 5.7% to 6.5%). The glycemic variability measured with CV also began to increase as *uGMI* increased over 5.7%. CGM metrics of individuals with prediabetes are sensitive to progressive changes in glycemic management, providing insight into early glucose patterns that may inform future research.

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