Biases in Glucose Metrics are Directly Related to Low Coverage of Continuous Glucose Monitoring

Insights from diverse populations

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Brief Report

Biases in Glucose Metrics are Directly Related to Low Coverage of Continuous Glucose Monitoring: Insights from diverse populations

Running title: Biases in Glucose Metrics

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Abbreviations: continuous glucose monitoring (CGM); intermittently scanned continuous glucose monitoring (isCGM); missing at random (MAR); missing complete at random (MCAR); missing not-at-random (MNAR); multiple daily insulin injections (MDI); Novo Nordisk (NN); Real-world data (RWD); time above range (TAR); time in range (TIR)

Keywords: continuous glucose monitoring, gaps, time in range, missing data, glycemic control, bias, flash glucose monitoring, missing not-at-random (MNAR)

Abstract

The aim was to investigate the association between CGM-data coverage and glycemic metrics.

This study included over 97,000 clinical study participants and real-world data from type 1 or type 2 diabetes treated with multiple daily insulin injections, closed-loop systems, or basal-only insulin regimens. Over 35 million days of CGM data were analyzed with multilevel modeling.

Low coverage was observed in 6.4–10.1% of days and was significantly associated with lower TIR across sources ($p<0.001$). Each 1% increase in coverage was associated with a within-person increase of 0.07–0.13% in mean daily TIR ($p<0.001$).

Our analysis shows that higher daily sensor coverage is significantly associated with higher daily TIR, suggesting that missing CGM data may be missing not-at-random (MNAR). Although low-coverage days are included in TIR calculations, they contribute fewer measurements and may underrepresent periods of poor glycemic control, potentially leading to a systematic overestimation and bias of overall TIR.

Introduction

Continuous glucose monitoring (CGM) has revolutionized diabetes care by providing real-time insights into glucose variability and facilitating the evaluation of glycemic control metrics such as time in range (TIR). TIR has emerged as a critical marker for assessing diabetes management and its potential long-term complications. As TIR gains prominence in clinical practice and research, its accurate estimation becomes essential for guiding therapeutic decisions and evaluating interventions (1).

However, the reliability of TIR and other CGM-derived metrics is contingent upon the quality and continuity of CGM data. Missing data, commonly referred to as CGM data gaps, poses a significant challenge to the accurate estimation of TIR (2). These gaps can arise from various factors, including sensor dislodgement, communication failures between the sensor and receiver, or user nonadherence. Despite advancements in CGM technology, data gaps remain a persistent issue, both in real-world settings and clinical trials. The influence of missing data gaps on the estimation of TIR is not well investigated.

The presence of CGM gaps introduces the potential for bias, whether periods with <70% coverage are excluded or not, unless data are missing at random (MAR) or missing complete at random (MCAR). It is not possible to conclude from the data itself whether data are MAR, but we may get an indication by studying the relationship between day-to-day coverage of CGM and glycemic control metrics. The aim of this study was to investigate the association between CGM-data coverage and glycemic metrics.

We show here that the MAR assumption is debatable, and that the gaps are likely related to missing not-at-random (MNAR) patterns. This emphasizes the need for addressing missing data in a careful way and ensuring good coverage to minimize biases that can distort the interpretation of glycemic control and hinder the ability to make evidence-based clinical decisions.

Research Design and Methods

Data material

This analysis included data from clinical trials and real-world data involving individuals with type 1 and type 2 diabetes:

i: The DiaMonT trial (3), an open-label RCT, enrolled 331 participants with insulin-treated T2DM. Conducted over three months in Denmark, participants were equally randomized to telemonitoring using CGM (Dexcom G6) or usual care.

ii: (4)The T1DiabetesGranada study (4) gathered four years of CGM data from 736 individuals with T1D. The study predominantly utilized the FreeStyle Libre 2, though first-generation devices were employed during the initial phase. Acknowledging the known performance discrepancies of the first generation device, it is important to note this as a limitation of the cohort.

iii: The IOBP trial (5), a multicenter RCT, assessed a closed-loop insulin delivery system for at-home use in 449 people with T1D (ages 6–79). Participants used either the iLet Bionic Pancreas with Dexcom G6 CGM or standard care for up to 13 weeks.

iiii: Connected pen (CP) real-world data from the Novo Nordisk (NN) digital health partners. All days with CGM data were collected from users of connected insulin pens who were also using a CGM and sharing their data anonymously with NN through a partner app (Abbott Libreview, Glooko app or Diasend app). The source data are from different CGM systems, and the model is not known.

Preprocessing and statistics

CGM data for individuals was assessed for each day, and unique days with CGM measurements were included for the analysis. The daily TIR (70-180 mg/dl), time above range (TAR, >180 mg/dl), and time below range (TBR <70 mg/dl) was calculated according to guidelines (6). Coverage (data completeness) for each day was calculated based on the sampling rate for the CGM sensor. For the data source where the model is unknown, the sampling rate was derived from the data.

A linear mixed-effects model was used to examine the association between TIR and sensor coverage, accounting for between and within-person variability in coverage. A random intercept was included, to model random differences between persons, not explained by CGM coverage. Furthermore, to assess differences in CGM Metrics between days with high data coverage (≥ 70%) and low data coverage (<70%) a Wilcoxon rank sum test was used to test for differences, considering a statistically significant $p < 0.05$.

Results

This study analyzed a combined cohort of individuals with type 1 and 2 diabetes treated with multiple daily insulin injections (MDI), closed-loop insulin delivery, or basal-only insulin regimens. A total of 97,988 participants contributed data, encompassing more than 35 million cumulative days of continuous glucose monitoring (CGM).

A significant association was identified between CGM data coverage and TIR, with lower data coverage being linked to reduced TIR ($p < 0.001$).

- **CP:** each 1% increase in average coverage across participants was associated with a 0.51% increase in mean TIR ($CI_{95\%}$: 0.495 to 0.518, $p<0.001$). Additionally, within-person daily deviations in coverage were also positively associated with TIR, with a 1% increase in coverage for any participant corresponding to a 0.069% increase in mean TIR ($CI_{95\%}$: 0.068 to 0.069, $p<0.001$). Median TIR was 42.6% vs. 57.2% for low and high data coverage days, respectively ($p < 0.001$).
- **T1DiabetesGranada:** a 1% increase in average coverage across participants corresponded to a 0.578% rise in mean TIR ($CI_{95\%}$:0.464-0.692, $p<0.001$), while within-person daily increases in coverage were linked to a 0.086% TIR gain ($CI_{95\%}$:0.081-0.092, $p<0.001$). Median TIR was significantly higher on high-coverage days (51.2%) compared to low-coverage days (62.1%, $p < 0.001$).
- **IOBP:** a 1% increase in average coverage across participants corresponded to a 0.813% rise in mean TIR ($CI_{95\%}$: 0.588-1.039, $p<0.001$), while within-person daily increases in coverage were linked to a 0.085% TIR gain ($CI_{95\%}$: 0.074-0.096, $p<0.001$). Median TIR was significantly higher on high-coverage days (54.3%) compared to low-coverage days (64.2%, $p < 0.001$).
- **DiaMonT:** a 1% increase in average coverage across participants corresponded to a 3.110% rise in mean TIR ($CI_{95\%}$: 2.227-3.993, $p<0.001$), while within-person daily increases

in coverage were linked to a 0.131% TIR gain ($CI_{95\%}$: 0.110-0.153, p<0.001). Median TIR was significantly higher on high-coverage days (52.3%) compared to low-coverage days (71.3%, p<0.001).

Figure 1 illustrates the daily TIR, TAR, TBR and data coverage for the individual data sources. Similar trends were observed across different countries, age groups and over 14-day periods, as shown in **SupplementaryMaterialS1**. Noteworthy, for the 14-day aggregation of data within-person differences are observed in the coverage range between 70-100%. In general, within-person deviations in coverage were positively associated with TIR, with a 1% increase in coverage for any participant corresponding to a 0.04% increase in mean TIR (95% CI:0.039-0.041, p < 0.001).

Discussion

Our analysis shows that higher daily sensor coverage both within-and between-person is significantly associated with higher TIR, suggesting that missing CGM data may be MNAR. The observed consistency of this relationship, spanning different diabetes types (type 1 and type 2), insulin therapy regimens (MDI, closed-loop systems, and basal-only), CGM devices, countries, and age groups, suggests that this is a generalizable phenomenon rather than one limited to specific subpopulations or technologies. Although low-coverage days are included in TIR calculations, they contribute fewer measurements and may underrepresent periods of poor glycemic control, potentially leading to a systematic overestimation of overall TIR.

We find a significant association between data coverage and TIR both between and within patients. The association between patients is likely confounded by several factors, for instance diabetes type and duration, treatment paradigm, CGM device type as well as demographic and socio-economic factors. Since these factors are not known, we cannot adjust for them directly. In contrast the within-patient association between coverage and TIR will only be confounded by time-varying factors for the same patient.

A plausible explanation for this association is the role of individual behavior in both CGM usage and overall diabetes self-management. Days with lower CGM data coverage likely reflect periods of disengagement from diabetes care, including intentional or unintentional removal, or neglect. These behavioral patterns may correlate with reduced adherence to other critical self-management activities, such as timely insulin administration, carbohydrate tracking, or meal planning (7). Conversely, days with high CGM data coverage may indicate greater attention to diabetes management and more consistent engagement with self-care practices. Previous studies support this hypothesis. For instance, a recent study by Danne et al. showed a strong association between frequency of data uploads to a diabetes management system and glycemic control (8) and another study by Hohendorff et al. showed an association between number of scans with an isCGM and glycemic control (9).

This interpretation raises important implications for clinical practice and research. In routine care, the bias introduced by periods of low data coverage may lead to an overestimation of glycemic control, as TIR calculations do not account for days with missing or incomplete CGM data. This is particularly concerning given that the non-observed periods appear to correspond with lower TIR. As such, clinicians should exercise caution when interpreting CGM metrics in patients with substantial data gaps, as these metrics may paint an overly optimistic picture of glycemic management. Likewise, insufficient coverage to determine CGM metrics may be an indication of suboptimal glycemic control, rather than just a technical issue. Similarly, in clinical research, this bias could affect the evaluation of interventions or treatments that rely on CGM-derived metrics as primary outcomes. Studies may inadvertently bias the effect of interventions, particularly if low-coverage days are systematically excluded from analyses. This underscores the need for standardized methods to handle CGM data gaps in both clinical and research contexts, such as sensitivity analyses or imputation techniques to estimate glycemic outcomes for missing periods. Certainly, excluding days with low coverage is not recommendable. Several studies have reported the effect of missing periods on 14-day estimations using modeling, however in future analysis the modeling should also investigate the effect of MNAR missing periods (2,10–12).

In clinical practice, it is recommended to use 14-days of data, calculate time in ranges based on the total period and only use the data for clinical decisions if the coverage is at least 70% (1,6). Our data is from studies with longer periods of data collection and no natural 14-day periods. We have therefore chosen to aggregate data at the daily level instead. The issue is fundamentally the same when analyzing 14-day periods, however, and we have conducted supplementary analyses based on 14-day periods, that show the same trends. In practice, the use of a threshold of >70% coverage ensures that data will have a reasonable quality to make clinical decisions, but our results still imply for instance that TIR will on average be smaller if the coverage is 75% compared to 95%.

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Disclaimer: The presented analysis included data from the T1DiabetesGranada / IOBP trial, but the analyses, content and conclusions presented herein are solely the responsibility of the authors and have not been reviewed or approved by trial group(s).

Ethics statement: The presented study is a reanalysis of existing and anonymized data from the T1DiabetesGranada / IOBP / DiaMonT clinical trials. The original study protocols and informed consent forms were approved by the institutional review board(s). Written informed consent was obtained from each participant prior to enrollment of each study: the Ethics Committee of Biomedical Research of the Province of Granada, Spain (CEIm/CEI GRANADA), protocol code K134665CRL, ethics portal code 0698-N-21; the Regional Ethical Committee of North Jutland, Denmark (N-20200068); ClinicalTrials.gov number(s): NCT04200313, NCT04981808

Data Availability Statement: The full raw data utilized in this study are not publicly available due to the inclusion of sensitive patient information, which is subject to strict confidentiality and privacy regulations. Access to the data is restricted to ensure compliance with ethical guidelines and to protect patient privacy. Requests for additional information or collaboration may be considered on a case-by-case basis, subject to appropriate ethical approval and data-sharing agreements.

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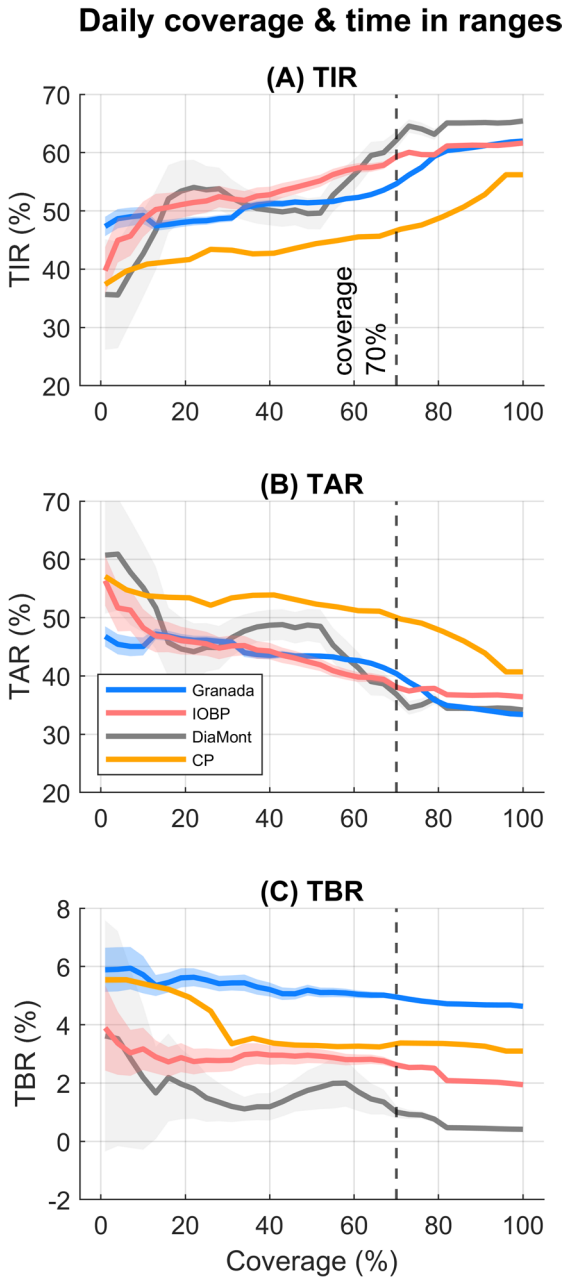

Figure 1 – Relationship between CGM coverage and Time in Range (TIR) (A), Time Above Range hyperglycemia (TAR) (B), and Time Below Range hypoglycemia (TBR) (C).

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	IOBP	DiaMont	T1DiabetesGranada	CP
Diabetes type	Type 1 diabetes	Type 2 diabetes	Type 1 diabetes	Mixed / Unknown
Treatment regimen	Closed loop	Basal only or Basal/Bolus	Basal/Bolus	Mixed / Unknown
Study duration	13 weeks	6 months	4 years	Mixed. Median: 323 days
n (subject)	449	329	736	96,474
Age, yrs	29 [13-49]	65 [54-65]	44 [30-56]	43 [31-56]
HbA1c, %	7.8 [7.10–8.49]	8.0 [7.01–8.68]	7.9 [7.1-8.9]	Unknown
Gender (female), %	47.7	38.4	50.7	44.9[1]
CGM sensor, type	Dexcom G6	Dexcom G6	FreeStyle Libre 1+2	Mixed / Unknown
CGM metrics				
Active monitoring days, n	52,648	21,124	257,046	35,908,822
Coverage, %	100 [96.2-100]	100 [99-100]	97.9 [89.6-100]	98.9 [92.7-99.6]
Low coverage days, %	6.4	4.70	10.1	8.9
Time-in-range, %	63.7 [47.9-76.0]	70.8 [46.2-87.8]	61.3 [42.4-77.9]	56.3 [33.9-75.8]
- Low coverage days	54.3 [32.7-73.4]	52.3 [19.6-80.0]	51.2 [24.1-76.4]	42.6 [12.5-71.5]
- High coverage days	64.2 [48.9-76.4]	71.3 [47.6-88.2]	62.1 [44-78]	57.2 [35.7-76.1]
Time-above-range, %	33.7 [21.5-49.7]	28.8 [11.1-53.5]	32.6 [15.6-53.6]	39.7 [19.3-63.8]
- Low coverage days	41.5 [22.4-65.4]	46.1 [15.1-79.6]	41.5 [13.9-72.7]	52.5 [21.7-86.1]
- High coverage days	33.3 [21.5-49.0]	28.1 [11.1-52.1]	32.3 [15.6-52.1]	38.9 [19.2-62.1]
Time-below-range, %	0.4 [0.0-2.9]	0.0 [0.0-0.0]	0.6 [0.0-6.2]	0 [0-3.35]
- Low coverage days	0.0 [0.0-3.3]	0.0 [0.0-0.0]	0.0 [0.0-3.9]	0 [0-1.54]
- High coverage days	0.7 [0.0-2.8]	0.0 [0.0-0.0]	1.1 [0.0-6.2]	0 [0-3.48]

Table 1 – Baseline and CGM characteristic for the four cohorts included in the analysis. Data is presented as either percentages or median [25-75 percentile].[1] Gender is not known for 93.9% of the cohort. Notice that 3 three studies (IOBP, DiaMont, T1DiabetesGranada) and the real-world cohort (CP) are different in duration, population and treatment regimen, and cannot be compared in terms of e.g. glycemic control. The pattern of interest here is the association between coverage and TIR, which is consistent across data sources.

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Supplementary material S1

S1 includes additional plots based on real-world CP NN partner data.

Daily aggregated values

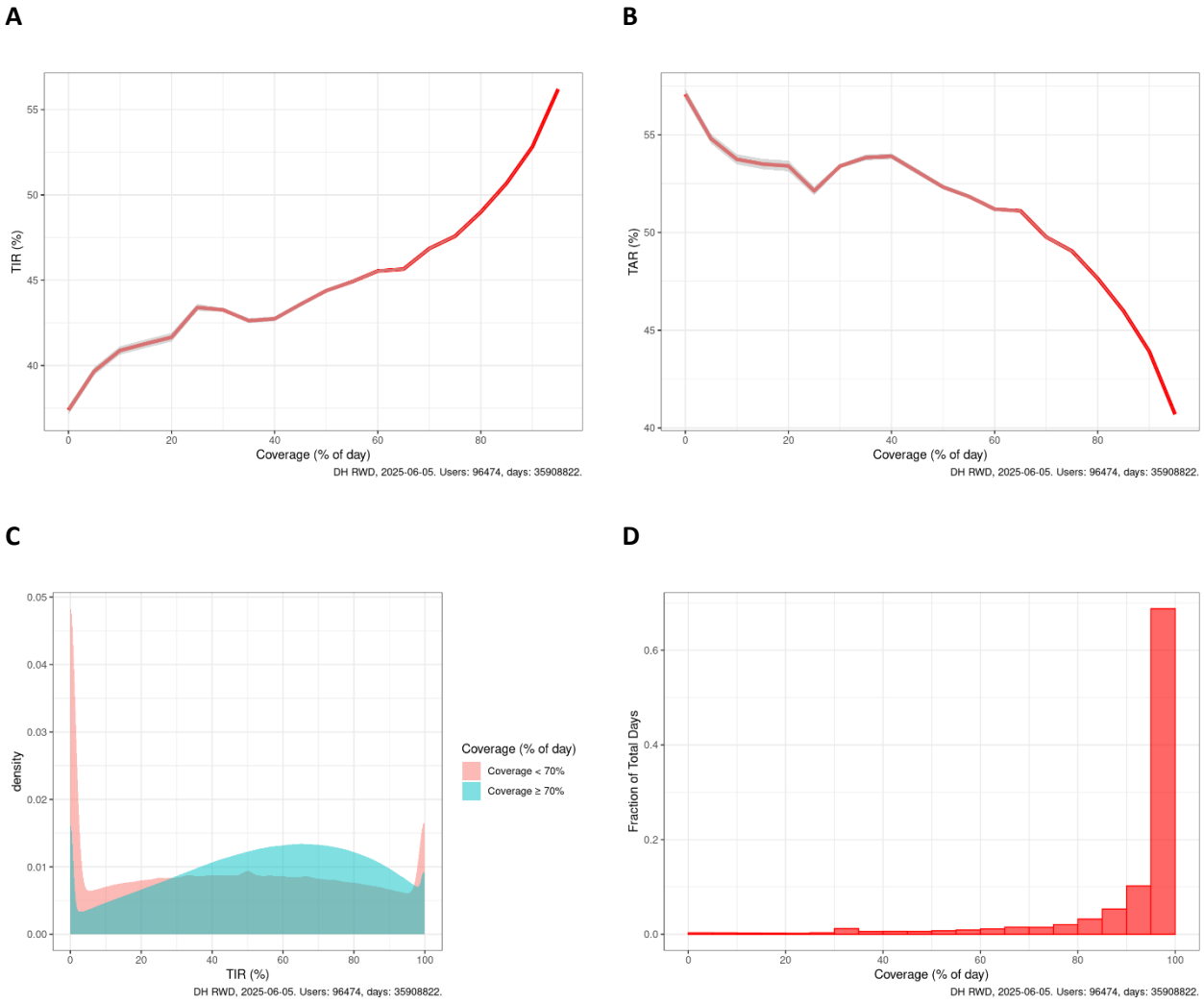

Figure S1 – (A) Association between Time in Range (TIR) and continuous glucose monitoring (CGM) coverage for individual days. (B) Association between Time Above Range (TAR) and CGM coverage for individual days. (C) Distribution of TIR, comparing days with <70% versus ≥70% CGM coverage. (D) Histogram depicting the distribution of CGM coverage across individual days.

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Age groups, daily aggregated values

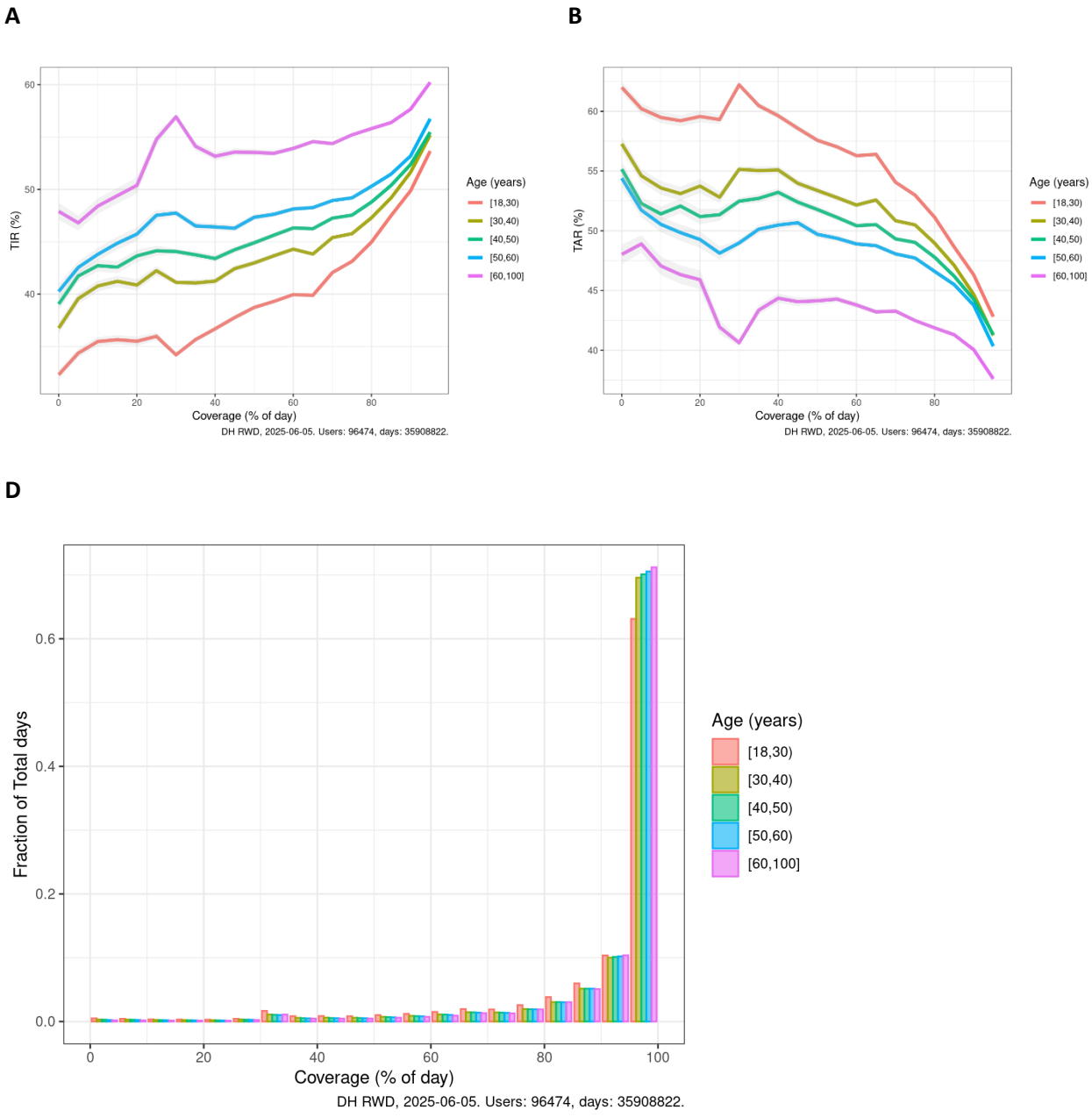

Figure S2 – (A) Association between Time in Range (TIR) and continuous glucose monitoring (CGM) coverage for age groups. (B) Association between Time Above Range (TAR) and CGM coverage for age groups. (C) Histogram depicting the distribution of CGM daily coverage across age groups.

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By country, daily aggregated values

Selecting the 9 countries with most participants.

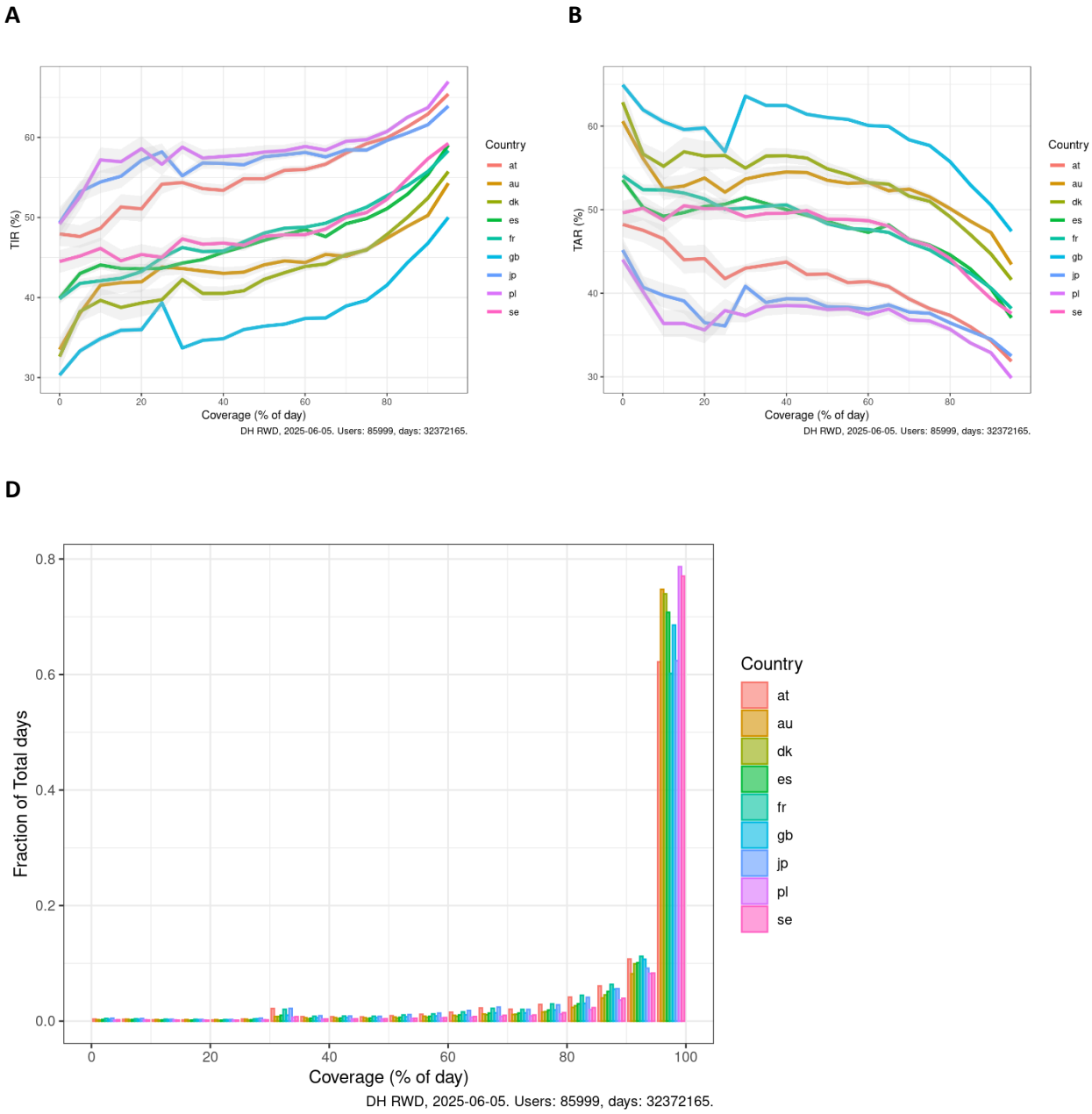

Figure S3 – (A) Association between Time in Range (TIR) and continuous glucose monitoring (CGM) coverage for countries. (B) Association between Time Above Range (TAR) and CGM coverage for countries. (C) Histogram depicting the distribution of CGM daily coverage across countries.

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14-day aggregated values

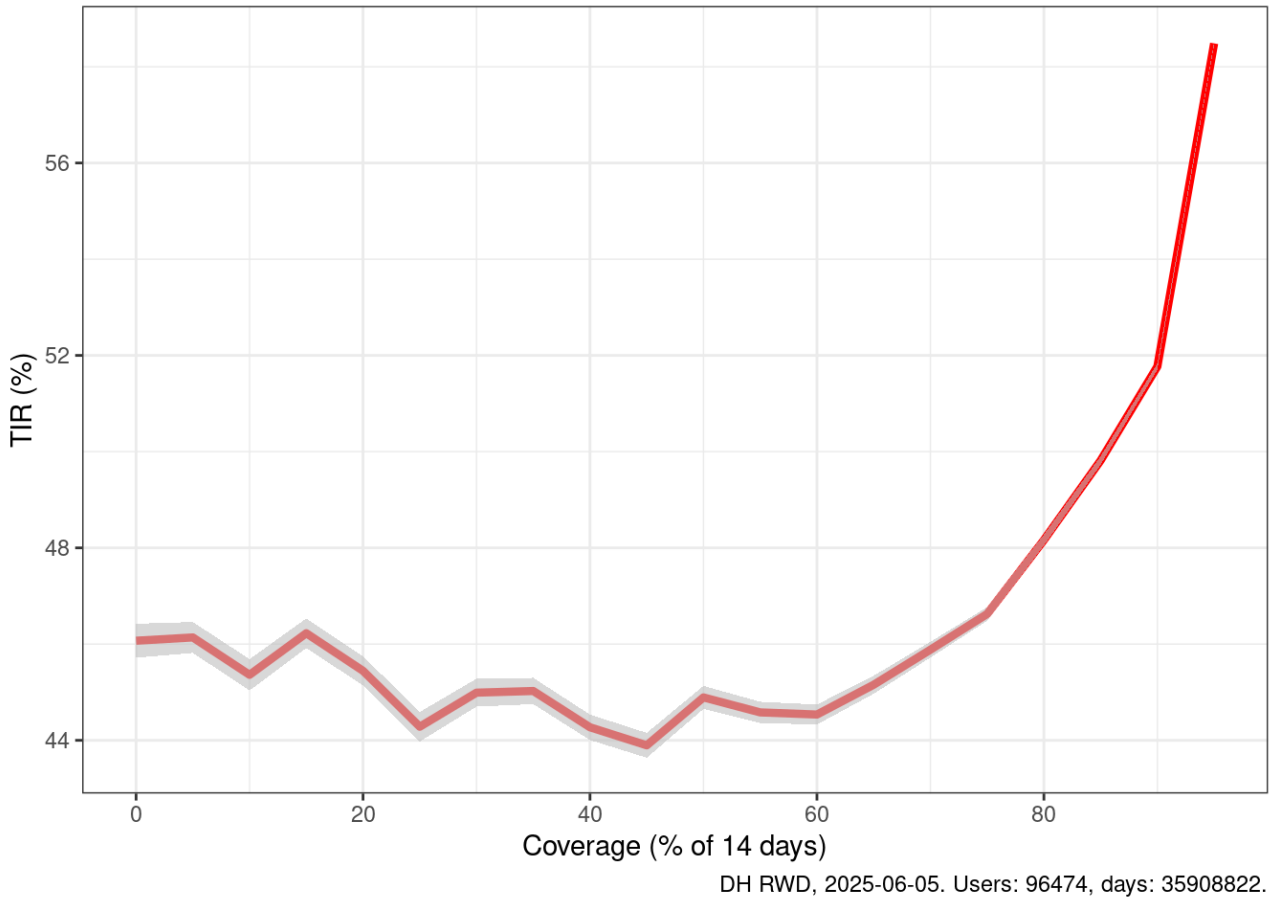

Figure S4 – Association between Time in Range (TIR) and continuous glucose monitoring (CGM) coverage for 14 aggregated days.

For the 14-day aggregated values, each 1% increase in average coverage across participants was associated with a 0.302% increase in mean TIR (95% CI:0.295-0.309, $p < 0.001$). Additionally, within-person deviations in coverage were also positively associated with TIR, with a 1% increase in coverage for any participant corresponding to a 0.04% increase in mean TIR (95% CI:0.039-0.041, $p < 0.001$).