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Original Research Article

Association of Time in Range Parameters Using Continuous Glucose Monitoring with Microvascular Complications in Patients with Type 2 Diabetes Mellitus

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Received: 06 Aug 2026 | Accepted: 16 Aug 2026 | Published: 19 Aug 2026

Abstract

Background: Type 2 diabetes mellitus (T2DM) is associated with progressive microvascular complications, including diabetic retinopathy, nephropathy, and neuropathy. Although glycated hemoglobin (HbA1c) remains the standard marker of glycemic control, it does not reflect daily glucose fluctuations or glycemic variability. Continuous glucose monitoring (CGM)-derived Time in Range (TIR) provides a comprehensive assessment of glucose patterns and may serve as an important marker associated with diabetes-related complications. This study aimed to evaluate the association between CGM-derived TIR parameters and microvascular complications in patients with T2DM.

Methods: This observational study included patients with T2DM who underwent continuous glucose monitoring. Demographic characteristics, clinical parameters, HbA1c levels, and CGM-derived metrics, including TIR, Time Above Range (TAR), Time Below Range (TBR), and glucose variability, were assessed. Microvascular complications were evaluated through appropriate clinical and laboratory assessments. The association between TIR parameters and microvascular complications was analyzed using appropriate statistical methods.

Results: A total of 200 patients with T2DM were included in the analysis. Microvascular complications were present in 59% of participants. Patients with microvascular complications had significantly lower TIR compared with those without complications (43.2 ± 15.6% vs 70.9 ± 13.8%, $p<0.001$). They also demonstrated higher HbA1c levels, increased TAR, and greater glucose variability. Lower TIR was significantly associated with diabetic retinopathy, nephropathy, and neuropathy. Multivariate analysis showed that reduced TIR remained independently associated with microvascular complications after adjustment for clinical factors and HbA1c.

Conclusion: CGM-derived Time in Range is significantly associated with microvascular complications in patients with T2DM and provides additional information beyond HbA1c for assessing glycemic control. Incorporation of TIR into routine diabetes management may improve risk stratification and support individualized strategies for prevention of diabetes-related complications.

Keywords: Type 2 diabetes mellitus; Continuous glucose monitoring; Time in Range; Glycemic variability; HbA1c; Diabetic retinopathy; Diabetic nephropathy; Diabetic neuropathy.

Introduction

Type 2 diabetes mellitus (T2DM) is a progressive metabolic disorder characterized by chronic hyperglycemia due to impaired insulin secretion, insulin resistance, or a combination of both. It is one of the most prevalent non-communicable diseases worldwide and poses a major public health challenge because of its increasing prevalence, healthcare burden, and long-term complications[1].

Persistent hyperglycemia results in structural and functional damage to various tissues, leading to diabetes-related complications. Among these, microvascular complications such as diabetic retinopathy (DR), diabetic nephropathy (DN), and diabetic peripheral neuropathy (DPN) are major causes of visual impairment, chronic kidney disease, disability, and reduced quality of life in individuals with diabetes[2].Optimal glycemic control is essential for preventing and delaying the progression of diabetes-related complications. Hemoglobin A1c (HbA1c) has traditionally been considered the standard biomarker for assessing long-term glycemic control and predicting diabetes-associated complications. [1,2] However, HbA1c represents average glucose levels over the preceding 2–3 months and does not provide information regarding short-term glucose fluctuations, glycemic variability, or episodes of hypo- and hyperglycemia. Furthermore, HbA1c values may be affected by factors such as age, ethnicity, hemoglobin variants, altered erythrocyte lifespan, hemolytic anemia, recent blood transfusion, chronic kidney disease, and pregnancy, leading to potential discrepancies between HbA1c levels and actual glycemic exposure. [3]Self-monitoring of blood glucose (SMBG) provides additional information regarding glucose levels but is limited by the need for frequent testing, inconvenience, and reduced adherence among patients. These limitations have highlighted the need for more comprehensive approaches to evaluate glycemic patterns.

Continuous glucose monitoring (CGM) has emerged as an important advancement in diabetes management by providing continuous assessment of glucose levels and detailed information regarding daily glucose fluctuations. CGM devices measure interstitial glucose concentrations at frequent intervals, usually every 1–5 minutes, enabling evaluation of multiple glycemic parameters, including average glucose, glucose variability, Time in Range (TIR), Time Above Range (TAR), and Time Below Range (TBR). [4] The glucose management indicator (GMI), calculated from CGM-derived average glucose values, provides an additional estimate of long-term glycemic status. [5]Among CGM-derived metrics, TIR has gained increasing clinical importance as a measure of glycemic quality. TIR represents the percentage of time glucose levels remain within the target range of 70–180 mg/dL (3.9–10.0 mmol/L). [4] Higher TIR reflects better glycemic control, whereas reduced TIR indicates prolonged exposure to abnormal glucose levels. International consensus guidelines recommend achieving a TIR of approximately 70% for most adults with diabetes, corresponding to an HbA1c target near 7%. [4] Studies have shown that a 10% increase in TIR is associated with an approximate 0.5% reduction in HbA1c, while even a 5% improvement in TIR may provide clinically meaningful benefits in patients with T2DM.[4,6]Although HbA1c remains an established predictor of microvascular complications, emerging evidence suggests that CGM-derived TIR may provide additional prognostic information. Lower TIR values have been associated with increased prevalence and severity of diabetic retinopathy, nephropathy, and neuropathy. [7,8] Reduced TIR reflects prolonged hyperglycemic exposure, which may promote oxidative stress, endothelial dysfunction, inflammation, and advanced glycation end-product formation, contributing to microvascular injury.[9]Sheng et al. [10] demonstrated that lower TIR values were associated with increased likelihood of diabetic retinopathy, diabetic nephropathy, and diabetic peripheral neuropathy among individuals with T2DM. However, the clinical significance of CGM-derived TIR parameters in predicting microvascular complications remains an evolving area requiring further investigation.[11,12]

Therefore, this study aimed to evaluate the association between CGM-derived Time in Range parameters and microvascular complications in patients with Type 2 diabetes mellitus.

Methodology:

The present study was conducted as an observational study to evaluate the association between continuous glucose monitoring (CGM)-derived Time in Range (TIR) parameters and microvascular complications among patients with Type 2 diabetes mellitus (T2DM).

Study Population

Patients diagnosed with Type 2 diabetes mellitus who attended the outpatient diabetes clinic or were admitted to the hospital during the study period were screened for eligibility. Participants were selected according to predefined inclusion and exclusion criteria.

Inclusion Criteria

- Patients fulfilling the following criteria were included in the study:
- Adults aged ≥18 years with a confirmed diagnosis of Type 2 diabetes mellitus.
- Patients who had undergone continuous glucose monitoring for assessment of glycemic parameters.
- Patients with available CGM data of adequate duration for calculation of Time in Range parameters.
- Patients willing to participate and provide informed consent.

Exclusion Criteria

Patients were excluded if they had:

- Type 1 diabetes mellitus or other specific types of diabetes.
- Pregnancy or gestational diabetes mellitus.
- Recent blood transfusion or conditions affecting red blood cell turnover that could interfere with HbA1c interpretation.
- Severe acute illness, malignancy, or other conditions likely to affect glycemic measurements.
- Incomplete CGM data or inadequate sensor wear duration.

Clinical and Demographic Assessment

Baseline demographic and clinical characteristics were recorded for all participants. Data regarding age, sex, duration of diabetes, body mass index (BMI), diabetes treatment regimen, presence of hypertension, and other relevant comorbidities were collected. A detailed clinical history and physical examination were performed for each participant.

Assessment of Glycemic Parameters

Hemoglobin A1c Measurement

HbA1c levels were measured using a standardized laboratory method. The most recent HbA1c value obtained within the study period was recorded and used for assessment of long-term glycemic control.

Continuous Glucose Monitoring Assessment

Continuous glucose monitoring was performed using a validated CGM device. The sensors were placed according to manufacturer instructions, and glucose readings were recorded at regular intervals from interstitial fluid measurements. CGM data were downloaded and analyzed using compatible software.

The following CGM-derived parameters were assessed:

- Time in Range (TIR): Percentage of time glucose levels remained within the target range of 70–180 mg/dL (3.9–10.0 mmol/L).
- Time Above Range (TAR): Percentage of time spent with glucose levels above the target range.
- Time Below Range (TBR): Percentage of time spent with glucose levels below the target range.
- Glucose variability parameters: Measures of fluctuations in glucose levels obtained from CGM data.

Only CGM recordings meeting the predefined criteria for adequate data completeness were included for analysis.

Assessment of Microvascular Complications

Microvascular complications were assessed using clinical evaluation and available laboratory and diagnostic investigations.

Diabetic Retinopathy

The presence and severity of diabetic retinopathy were assessed through ophthalmological evaluation, including fundus examination and/or retinal imaging, as appropriate.

Diabetic Nephropathy

Renal involvement was evaluated by assessment of urinary albumin excretion and renal function parameters, including estimated glomerular filtration rate (eGFR), wherever applicable.

Diabetic Peripheral Neuropathy

Peripheral neuropathy was assessed through clinical neurological examination using validated assessment methods, including evaluation of sensory function, vibration perception, and neuropathic symptoms.

Study Outcomes

The primary outcome of the study was to determine the association between CGM-derived Time in Range parameters and the presence of microvascular complications in patients with T2DM.Secondary outcomes included evaluation of the relationship between other CGM parameters, HbA1c levels, and individual microvascular complications, including diabetic retinopathy, diabetic nephropathy, and diabetic peripheral neuropathy.

Statistical Analysis

Data were analyzed using SPSS statistical software. Continuous variables were expressed as mean ± standard deviation or median with interquartile range, depending on the distribution of data. Categorical variables were presented as frequencies and percentages.The association between TIR parameters and microvascular complications was evaluated using appropriate statistical tests. Comparisons between groups with and without microvascular complications were performed using independent t-test, Mann–Whitney U test, Chi-square test, or Fisher's exact test, as applicable.

Correlation analysis was performed to assess the relationship between CGM-derived parameters and clinical variables. Multivariable regression analysis was performed to identify independent associations between TIR and microvascular complications after adjusting for potential confounding factors.

A p-value of <0.05 was considered statistically significant.

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical

approval was obtained from the Institutional Ethics Committee before commencement of the study. All participants provided written informed consent, and confidentiality of patient information was maintained throughout the study.

Results:

A total of 200 patients with Type 2 diabetes mellitus (T2DM) were included in the final analysis. The mean age of the study population was 56.4 ± 10.2 years, and 118 (59%) participants were male. The mean duration of diabetes was 9.3 ± 5.6 years. The mean body mass index (BMI) was 27.1 ± 4.2 kg/m². Hypertension was present in 112 (56%) participants, while dyslipidemia was observed in 128 (64%) participants. The majority of participants were receiving oral antidiabetic medications, while 38% were on insulin therapy. The baseline demographic and clinical characteristics are presented in Table 1.

Table 1. Baseline demographic and clinical characteristics of study participants (n=200)

Variable	Value
Age (years), mean ± SD	56.4 ± 10.2
Male sex, n (%)	118 (59%)
Duration of diabetes (years), mean ± SD	9.3 ± 5.6
BMI (kg/m²), mean ± SD	27.1 ± 4.2
Hypertension, n (%)	112 (56%)
Dyslipidemia, n (%)	128 (64%)
Insulin therapy, n (%)	76 (38%)
HbA1c (%), mean ± SD	8.1 ± 1.4

The CGM-derived glycemic parameters are summarized in Table 2. The mean Time in Range (TIR) among study participants was 54.6 ± 18.7%. The mean percentage of time spent above the recommended glucose range was 41.2 ± 19.4%, whereas time below range was minimal (2.1 ± 1.8%). The mean glucose variability assessed by coefficient of variation (CV) was 34.5 ± 8.2%.

Table 2. Continuous glucose monitoring-derived glycemic parameters (n=200)

CGM parameter	Mean ± SD
Mean glucose (mg/dL)	168.5 ± 35.6
Time in Range (70–180 mg/dL), %	54.6 ± 18.7
Time Above Range >180 mg/dL, %	41.2 ± 19.4
Time Above Range >250 mg/dL, %	16.5 ± 12.8
Time Below Range <70 mg/dL, %	2.1 ± 1.8
Glucose SD (mg/dL)	58.3 ± 18.6
Coefficient of variation (%)	34.5 ± 8.2

Among the 200 participants, 118 (59%) had at least one microvascular complication. Diabetic retinopathy was identified in 62 (31%) patients, diabetic nephropathy in 74 (37%), and diabetic peripheral neuropathy in 68 (34%) participants. The distribution of microvascular complications is shown in (Table 3, Figure 1)

Table 3. Distribution of microvascular complications among study participants (n=200)

Microvascular complication	n (%)
Any microvascular complication	118 (59%)
Diabetic retinopathy	62 (31%)
Mild non-proliferative diabetic retinopathy	36 (18%)
Moderate/severe diabetic retinopathy	26 (13%)
Diabetic nephropathy	74 (37%)
Microalbuminuria	52 (26%)
Macroalbuminuria	22 (11%)
Diabetic peripheral neuropathy	68 (34%)

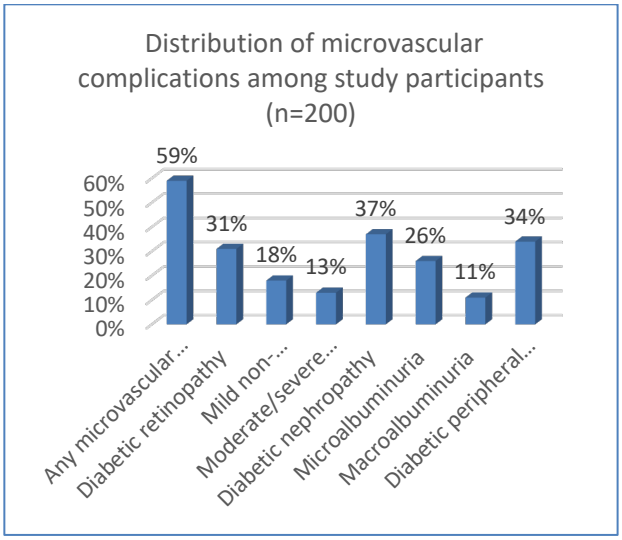

Figure 1 Distribution of microvascular complications among study participants (n=200)

Patients with microvascular complications demonstrated significantly poorer glycemic profiles compared with those without complications. Mean TIR was significantly lower among participants with microvascular complications (43.2 ± 15.6% vs 70.9 ± 13.8%, p<0.001). In contrast, HbA1c and Time Above Range values were significantly higher in patients with complications. The comparison of glycemic parameters between groups is presented in (Table 4, Figure 2)

Table 4. Comparison of glycemic parameters according to presence of microvascular complications

Parameter	Without complications (n=82)	With complications (n=118)	p-value
HbA1c (%)	7.3 ± 1.1	8.7 ± 1.4	<0.001
TIR (%)	70.9 ± 13.8	43.2 ± 15.6	<0.001
TAR >180 mg/dL (%)	25.4 ± 12.6	52.1 ± 18.4	<0.001
TAR >250 mg/dL (%)	8.2 ± 7.4	22.3 ± 13.5	<0.001
TBR <70 mg/dL (%)	1.8 ± 1.5	2.3 ± 2.0	0.08
CV (%)	30.2 ± 6.7	37.5 ± 8.4	<0.001

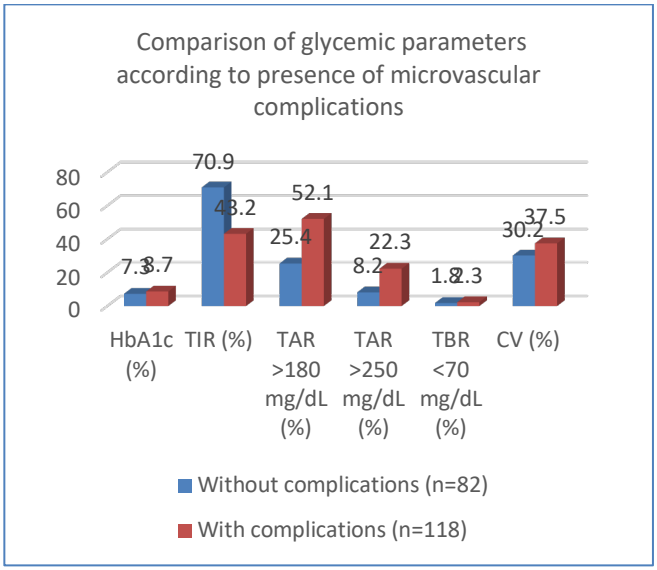

Figure 2 Comparison of glycemic parameters according to presence of microvascular complications

Participants were categorized according to TIR achievement. A progressive increase in the prevalence of microvascular complications was observed with declining TIR levels. Patients with TIR <50% had a significantly higher prevalence of retinopathy, nephropathy, and neuropathy compared with those achieving TIR ≥70% (Table 5, Figure 3).

Table 5. Association between TIR categories and microvascular complications

TIR category	Number of patients	Retinopathy n (%)	Nephropathy n (%)	Neuropathy n (%)
≥70%	48	8 (16.7)	10 (20.8)	9 (18.8)
50–69%	72	20 (27.8)	26 (36.1)	23 (31.9)
<50%	80	34 (42.5)	38 (47.5)	36 (45.0)
p-value		0.006	0.004	0.008

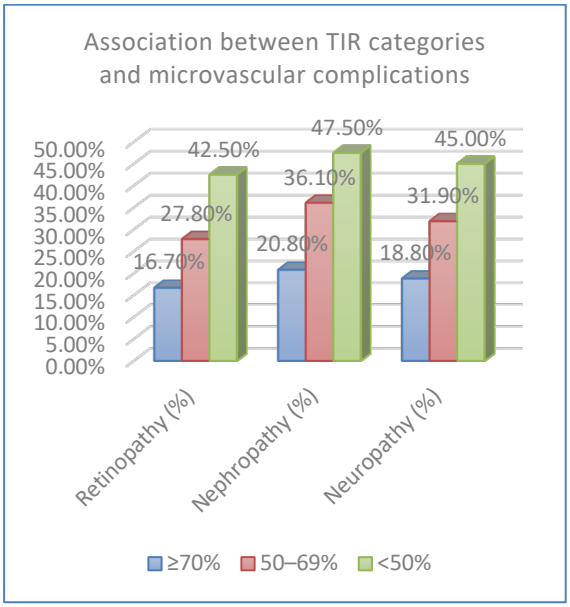

Figure 3 Association between TIR categories and microvascular complications

Multivariate logistic regression analysis demonstrated that lower TIR was independently associated with the presence of microvascular complications after adjustment for age, duration of diabetes, and HbA1c. Every 10% reduction in TIR was associated with increased odds of developing microvascular complications (OR 1.42, 95% CI 1.18–1.72, p<0.001). The regression analysis is presented in Table 6.

Table 6. Multivariate logistic regression analysis for predictors of microvascular complications

Variable	Odds Ratio (OR)	95% Confidence Interval	p-value
TIR (per 10% decrease)	1.42	1.18–1.72	<0.001
HbA1c (per 1% increase)	1.31	1.08–1.59	0.006
Duration of diabetes (per year increase)	1.06	1.01–1.12	0.018
Age (per year increase)	1.02	0.99–1.05	0.11
Hypertension	1.54	0.92–2.58	0.09

Discussion

The present study evaluated the association between continuous glucose monitoring (CGM)-derived Time in Range (TIR) parameters and microvascular complications among patients with Type 2 diabetes mellitus (T2DM). In this study of 200 individuals with T2DM, microvascular complications were present in 59% of participants. Patients with microvascular complications had significantly lower TIR compared with those without complications (43.2 ± 15.6% vs 70.9 ± 13.8%, p<0.001). In addition, patients with complications demonstrated higher HbA1c levels, increased Time Above Range (TAR), and greater glucose variability. Multivariate analysis showed that reduced TIR remained independently associated with microvascular complications after adjustment for age, duration of diabetes, and HbA1c. These findings suggest that CGM-derived TIR may provide additional clinical information beyond conventional HbA1c assessment.HbA1c has been considered the standard marker for assessing long-term glycemic control and predicting diabetes-related complications. However, HbA1c reflects only average glucose exposure and does not capture daily glucose fluctuations, glycemic variability, or episodes of hypo- and hyperglycemia. CGM technology overcomes some of these limitations by providing detailed glucose profiles and allowing assessment of multiple parameters, including TIR, TAR, TBR, and glucose variability. The increasing use of TIR reflects a shift from evaluating only the quantity of hyperglycemia to assessing the overall quality of glycemic control. International consensus recommendations have suggested achieving a TIR of approximately 70% for most adults with diabetes, as this corresponds approximately to an HbA1c level near 7%. [13] In the present study, the mean TIR was 54.6 ± 18.7%, indicating that a large proportion of patients failed to achieve the recommended glycemic target. Patients with microvascular complications had a substantially lower TIR (43.2 ± 15.6%) compared with those without complications (70.9 ± 13.8%). These findings are consistent with previous studies demonstrating an inverse relationship between TIR and diabetes-related complications. Raj et al., in a systematic review involving 11 studies and 13,987 patients with T2DM, reported that higher CGM-derived TIR was associated with a lower risk of diabetic retinopathy, diabetic nephropathy, and diabetic peripheral neuropathy. The review demonstrated that every 10% increase in TIR was associated with reduction in albuminuria, decreased severity of diabetic retinopathy, and lower prevalence of neuropathy. [13]The association between TIR and diabetic retinopathy observed in our study supports previous evidence that prolonged exposure to hyperglycemia contributes to retinal microvascular injury. In our cohort, diabetic retinopathy was identified in 31% of participants, and those with retinopathy had lower TIR values compared with participants without retinal involvement. Similar findings were reported by studies included in the systematic review by Raj et al., where reduced TIR was associated with

increased severity of diabetic retinopathy. The relationship between poor TIR and retinopathy may be explained by persistent glucose excursions causing oxidative stress, endothelial dysfunction, inflammation, and accumulation of advanced glycation end products, resulting in progressive retinal vascular damage.In the current study, diabetic nephropathy was present in 37% of participants, and lower TIR was significantly associated with renal involvement. These findings are comparable with previous studies demonstrating that reduced TIR is associated with markers of diabetic kidney disease. Raj et al. reported that increased TIR was associated with reduced urinary albumin-to-creatinine ratio, although the association with estimated glomerular filtration rate was less consistent. This suggests that TIR may reflect early renal microvascular injury and may be useful for identifying patients at increased risk of diabetic kidney disease. [13] Similarly, our study demonstrated an association between reduced TIR and diabetic peripheral neuropathy. Neuropathy was observed in 34% of participants, with affected individuals showing poorer CGM profiles characterized by lower TIR and increased glucose variability. These results are consistent with previous evidence showing that lower TIR is associated with increased prevalence of diabetic peripheral neuropathy and cardiac autonomic neuropathy. Fluctuating glucose levels may contribute to nerve damage through mechanisms involving oxidative stress, mitochondrial dysfunction, inflammatory activation, and impaired microvascular blood flow.[13] An important finding of our study was that TIR remained significantly associated with microvascular complications even after adjustment for HbA1c. This indicates that TIR may provide complementary information that cannot be obtained from HbA1c alone. Patients with similar HbA1c values may have markedly different glucose profiles, with differences in glucose excursions and variability potentially influencing the development of complications. Therefore, CGM-derived parameters may improve risk stratification and allow earlier identification of individuals requiring intensified therapeutic interventions.The biological basis for the relationship between reduced TIR and microvascular complications is multifactorial. Increased time spent above the target glucose range represents prolonged exposure to hyperglycemia, which promotes endothelial dysfunction, oxidative stress, inflammation, and formation of advanced glycation end products. These processes contribute to damage of small blood vessels in the retina, kidneys, and peripheral nerves. Additionally, increased glucose variability may independently contribute to vascular injury, even when average glucose levels appear acceptable.

The findings of this study have important clinical implications. While HbA1c remains an essential parameter for diabetes monitoring, incorporation of CGM-derived metrics such as TIR may provide a more comprehensive assessment of glycemic status. Improving TIR may represent an additional therapeutic goal alongside HbA1c reduction, particularly in patients at high risk for microvascular complications.The present study had certain limitations. First, the cross-sectional design limited the ability to establish a causal relationship between reduced TIR and development of microvascular complications. Second, the sample size was relatively limited, and the duration of CGM monitoring may influence the accuracy of calculated glucose metrics. Third, residual confounding factors such as medication changes, lifestyle factors, and duration of undiagnosed hyperglycemia could not be completely excluded. Future prospective multicenter studies with longer follow-up are required to determine whether improvement in TIR can prevent or delay microvascular complications.

Conclusion

In patients with Type 2 diabetes mellitus, lower continuous glucose monitoring-derived Time in Range (TIR) was significantly associated with a higher prevalence of microvascular complications. TIR provides additional information regarding glycemic control beyond HbA1c by capturing daily glucose fluctuations and overall glycemic exposure. CGM-derived TIR may serve as a valuable marker for identifying patients at increased risk of diabetic retinopathy, nephropathy, and neuropathy. Incorporation of TIR into routine diabetes management may support individualized treatment strategies and improve prevention of diabetes-related microvascular complications.

Limitations

This study had certain limitations, including its observational design, which limited the ability to establish a causal relationship between Time in Range parameters and microvascular complications. The sample size and study duration may have restricted the generalizability of the findings. Additionally, variations in CGM monitoring duration, treatment regimens, and other unmeasured confounding factors may have influenced the observed associations. Further large-scale, prospective studies with longer follow-up are required to confirm these findings.

Ethical approval

Ethical approval for this study was obtained from the Institutional Ethics Committee prior to the commencement of the study. The study was conducted in accordance with the ethical principles

outlined in the Declaration of Helsinki and applicable institutional guidelines.

Informed Consent

Written informed consent was obtained from all participants prior to their enrolment in the study.

Funding Statement

The authors received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest Declaration

The authors declare no conflict of interest.

Data Availability Statement

All data generated or analysed during this study are available from the corresponding author upon reasonable request.

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