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ORIGINAL ARTICLE

Dynamics of Hemoglobin A1c, Body Mass Index, and Rates of Severe Hypoglycemia in 4434 Adults with Type 1 or Type 2 Diabetes After Initiation of Continuous Glucose Monitoring

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Abstract

Background: Continuous glucose monitoring (CGM) might have beneficial effects on glycemic control and body mass index (BMI) in adults with type 1 (T1D) or type 2 diabetes (T2D).

Methods: The diabetes prospective follow-up registry was used to identify individuals with T1D or T2D ≥18 years starting CGM management in 2015 or later and follow-up information available. Hemoglobin A1c (HbA1c), BMI, and event rates of severe hypoglycemia in the year before CGM start were compared with two follow-up periods: (1) CGM use for 3–6 months and (2) CGM use for >6 months. Repeated measurements linear and negative binomial regressions were used (adjustment for sex, age at diabetes onset, and baseline parameters) and stratified by diabetes type.

Results: Mean follow-up time was 1.8 years in T1D ($n = 2994$) and 1.9 years in T2D ($n = 1440$). In T1D, adjusted mean HbA1c decreased significantly from 7.65% (95% confidence interval: 7.62–7.68) at baseline to 7.54% (7.51–7.57) during follow-up. BMI increased slightly (baseline: 25.4 kg/m^2 [25.3–25.5], follow-up >6 months: 25.8 kg/m^2 [25.7–25.9]), whereas event rates of severe hypoglycemia were significantly lower after >6 months with CGM (9.0 events/100 patient-years [PY; 8.0–10.1]) compared with baseline (11.3 events/100 PY [10.4–12.2]) in adults with T1D. In T2D, HbA1c decreased from 7.21% (7.17%–7.25%) to 7.00% (6.95%–7.04%) and BMI did not change after CGM initiation.

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Conclusion: Our results provide real-world evidence on CGM management in adult individuals with T1D or T2D. We suggest strengthening patients' and physicians' readiness toward diabetes technology in T2D and more openness of health insurance to cover cost based on proven benefits.

Keywords: Type 1 diabetes, Type 2 diabetes, Continuous glucose monitoring, Glycemic control, Real-world evidence.

Introduction

The use of continuous glucose monitoring (CGM) systems has increased over the past years[1,2] and new devices are introduced every year.[3] The proportion of CGM users in adult individuals with diabetes is significantly lower compared with the pediatric population.[1,2] Results on type 2 diabetes (T2D), especially from observational studies in real-world settings, are rare so far.[3,4] Randomized controlled trials comparing CGM use with self-monitoring blood glucose management have shown beneficial effects of CGM management on hemoglobin A1c (HbA1c) and episodes of hypoglycemia in adult individuals with type 1 diabetes (T1D).[5–7] However, a reduction in event rates of severe hypoglycemia has been observed in some[6,7] but not all studies,[3,5] as clinical trials did not have enough power to detect these effects owing to rare events and low sample size.

The DIAMOND study on 158 adult individuals with T2D with multiple daily insulin injections and a baseline mean HbA1c of 8.5% (standard deviation [SD] 0.6%) reported an HbA1c improvement of 0.8% (95% confidence interval [CI]: −1.0 to −0.7) in CGM users compared with 0.5% (−0.7 to −0.3) in a control group with traditional blood glucose monitoring after 24 weeks.[8]

Moreover, Martens et al. evaluated the effectiveness of CGM in adult individuals with T2D using less-intensive insulin regimens managed by primary care clinicians.[9] HbA1c mean was 9.1% (SD 1.0%) at randomization and a stronger HbA1c improvement with CGM (−1.1% [SD 1.5]) compared with traditional blood glucose monitoring (−0.6% [SD 1.2]) was found after 8 months.[9] A retrospective cohort study from Northern California including 41,753 adult individuals with insulin-treated diabetes (5673 T1D, 36,080 T2D) reported significant decreases in HbA1c and in hospitalizations for severe hypoglycemia in association with CGM initiation.[4]

Our objectives were to investigate potential beneficial effects of CGM initiation in individuals ≥18 years with T1D or T2D on HbA1c, body mass index (BMI), and event rates of severe hypoglycemia using data of the diabetes prospective follow-up registry (DPV). DPV captures data from diabetes specialist care and enables to study treatment and outcomes of people with diabetes in a multicenter, real-world setting.

Methods

Study population and covariates

The multicenter, DPV comprises pediatric as well as adult health care facilities.[10,11] Among 507 collaborators, 456 centers are in Germany, 46 in Austria, 4 in Switzerland, and 1 center in Luxembourg. In total 618,903 individuals with diabetes of all age groups were documented in the DPV initiative. Semi-annually, locally documented data are transmitted to Ulm University (Germany) in pseudonymized form and in encrypted archives. After validation, data are aggregated into an anonymized, cumulative database. Data collection and analysis for benchmarking and diabetes research were approved by the Ethics Committee of Ulm University (No. 314/21) and by local review boards of the participating centers. Individuals with T1D or T2D ≥18 years of age with CGM initiation in 2015 or later were included in the underlying study.

Demographic and clinical data included sex, current age, age at diabetes onset, BMI (kg/m^2), HbA1c (% or mmol/mol), diabetes treatment (conventional insulin therapy (≤3 injection time-points per day), intensive insulin therapy (4–8 injection time-points per day), insulin pump, oral antidiabetic medication), daily insulin dose (IU/kg), and systolic and diastolic blood pressure (mmHg). The multiple of the mean transformation method was used to standardize HbA1c values to the Diabetes Control and Complications Trial (DCCT) reference range of 4.05%–6.05% (20.7–42.6 mmol/mol).[12] Severe hypoglycemia was defined as an event requiring assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions.[13] Events of hypoglycemia were actively enquired and recorded at each visit using the DPV documentation software.[10] The year before CGM initiation was defined as the baseline period. HbA1c, BMI, and event rates of severe hypoglycemia at baseline were compared with two follow-up periods: (1) CGM use for 3–6 months and (2) CGM use for >6 months. Only individuals with documented information on the respective outcomes at baseline and during the two follow-up periods were included.

Statistical analysis

Continuous variables are presented as median with lower and upper quartiles. Binary variables are presented as percentages in the descriptive analyses. To study changes in outcome parameters during follow-up, repeated measurements analyses were conducted with a banded autoregressive covariance (Toeplitz) structure.[14] Linear regression was used to investigate changes in HbA1c and BMI and negative binomial regression were used for event rates of severe hypoglycemia. All models were adjusted for sex, age at diabetes onset, and respective baseline parameters. Analyses were stratified by diabetes type. We conducted additional analyses stratifying by HbA1c at baseline categorized as <7%, 7% to <8%, and ≥8% for each diabetes type separately. For individuals with T2D we implemented a further sensitivity analysis including only individuals with insulin therapy at baseline. Regression results are presented as adjusted least square means or event rates per 100 patient-years (PY)

together with 95% CIs. Statistical analyses were conducted using SAS version 9.4 (build TS1M7; SAS Institute, Inc., Cary, NC, USA) and a two-sided *P*-value of <0.05 was considered statistically significant.

Results

Of the 618,908 documented individuals with diabetes in DPV, 579,346 had T1D or T2D and of these 509,337 were ≥18 years of age (Fig. 1). In 2015 or later, 9851 individuals started CGM management. Information on the year before CGM initiation (baseline period) and on the two follow-up periods was available for 4434 individuals with T1D ($n = 2994$) or T2D ($n = 1440$). Baseline characteristics of the included individuals with T1D and T2D are given in Table 1. Median age in individuals with T1D was 19.9 years (Q1: 18.2, Q3: 45.8) and median HbA1c was 7.4% (6.8, 8.3). Fifty-three percent of the individuals with T1D were men and half of them used an insulin pump. Individuals with T2D had a median age of 67.5 years (58.8, 76.2) at baseline and HbA1c was 7.0% (6.4, 7.8). Proportion of people with T2D treated with insulin was 46% and 56% were men.

Mean follow-up time was 1.8 years in individuals with T1D and 1.9 years in T2D. Results from repeated measurements analyses on changes in outcomes from baseline in T1D are given in Figure 2. Adjusted HbA1c decreased significantly from 7.65% (95% CI: 7.62–7.68) at baseline to 7.54% (7.51–7.57) after 3–6 months with CGM and remained stable after >6 months with CGM (Fig. 2A). BMI increased slightly in T1D (baseline: 25.4 kg/m^2 [25.3–25.5], follow-up >6 months: 25.8 kg/m^2 [25.7–25.9]) (Fig. 2B). Moreover, we found significantly lower event rates of severe hypoglycemia (9.0 events/100 PY [8.0–10.1]) after a follow-up period of >6 months with CGM compared with the baseline period (11.3 events/100 PY [10.4–12.2]; Fig. 2C).

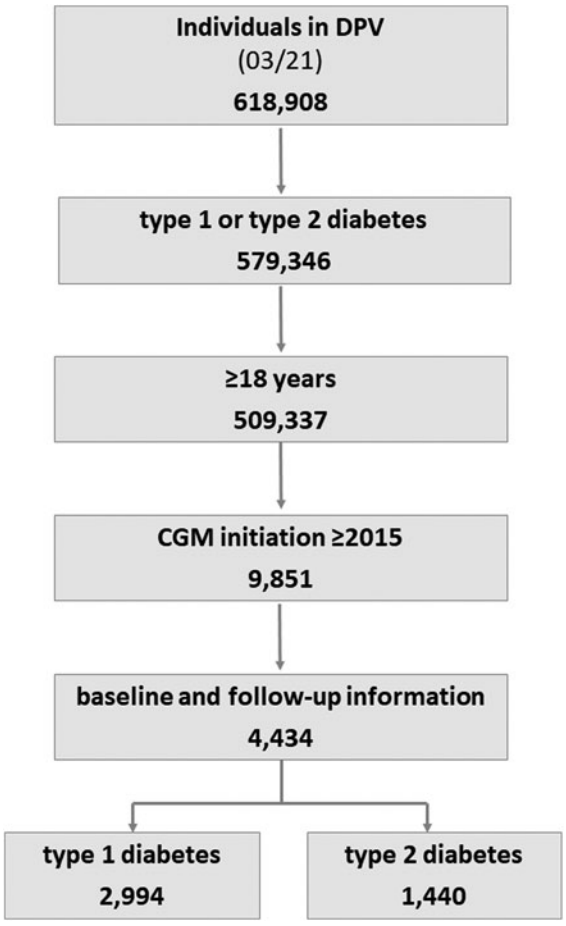

FIG. 1. Flow chart of included study participants.

CGM management was associated with a reduction in mean HbA1c in T2D from 7.21% (7.17%–7.25%) at baseline to 7.00% (6.95%–7.04%) after 3–6 months (Fig. 3A). We observed no significant change in BMI in people with T2D (Fig. 3B). Event rates of severe hypoglycemia in T2D were generally low and were slightly but nonsignificantly lower with CGM (>6 months use: 1.3 events/100 PY [0.9–1.7] compared with baseline (1.7 events/100 PY [1.4–2.1]; Fig. 3C).

Results stratified by HbA1c baseline categories revealed that in T1D and T2D decreases in HbA1c with CGM use were strongest in individuals with a HbA1c ≥8% at baseline (Supplementary Figs. S1 and S2). In individuals with T1D with HbA1c ≥8% at baseline, HbA1c decreased from 9.2% (9.1%–9.3%) to 8.7% (8.6%–8.8%) with CGM use for >6 months (Supplementary Fig. S1A). BMI increased slightly with all HbA1c baseline categories and event rates of severe hypoglycemia decreased significantly in individuals with T1D with a baseline HbA1c <7% (12.2 events/100 PY [10.7–13.8] to 6.3 events/100 PY [5.0–8.0]; Supplementary Fig. S1B, C). Individuals with T2D with HbA1c ≥8% at baseline showed a HbA1c reduction from 9.1% (8.9%–9.2%) to 7.9% (7.7%–8.1%) (Supplementary Fig. S2A). A reduction in BMI was reported for the subgroup with a baseline HbA1c 7% to <8% (32.7 kg/m^2 [32.3–33.1] to 32.5 kg/m^2 [32.1–33.0]; Supplementary Fig. S2B). Owing to the small number of events, severe hypoglycemia was not stratified by HbA1c baseline categories in T2D. Including only individuals with T2D treated with insulin did not change the results (Supplementary Fig. S3).

Discussion

Results of the DPV registry indicate slight, but beneficial effects of CGM management on glycemic control in T1D and T2D in a real-world setting. After a mean follow-up time of 1.8 years, HbA1c and event rates of severe hypoglycemia decreased significantly in individuals with T1D, whereas BMI increased slightly after CGM initiation. We also observed a significant reduction in HbA1c in individuals with T2D with or without insulin therapy using CGM for a mean follow-up time of 1.9 years. No significant changes in BMI and event rates of severe hypoglycemia were found in T2D.

Our results confirm reports from clinical trials showing reductions in HbA1c in adult individuals with T1D, especially in those with poor glycemic control at baseline (HbA1c ≥8%).[5,6] However, a recent observational study in adult individuals with T1D documented in the US T1D Exchange Registry (T1DX) reported an increase in HbA1c levels over time despite an increase in CGM use.[15] A transatlantic comparison in metabolic control showed significant differences in HbA1c across the lifespan in individuals with T1D between the T1DX and DPV registry, which might be an explanation for the contrasting results.[16] We observed a significant decrease in event rates of severe hypoglycemia

Table 1. Baseline Characteristics of the Included Individuals with Type 1 ($N=2994$) and Type 2 Diabetes ($N=1440$)

	T1D[a]	*T2D*[b]
Patient characteristics	*Median (Q1, Q3)*	*Median (Q1, Q3)*
Age at initiation of CGM (years)	19.9 (18.2, 45.8)	67.5 (58.8, 76.2)
Age at diabetes onset (years)	13.1 (8.6, 22.5)	52.3 (43.9, 60.6)
Diabetes duration (years)	10.7 (5.9, 18.1)	13.2 (7.8, 19.6)
BMI (kg/m^2)	24.6 (22.2, 27.6)	30.8 (27.5, 35.3)
BMI-SDS	0.3 (–0.5, 1.0)	0.8 (–0.1, 1.6)
HbA1c (%)	7.4 (6.8, 8.3)	7.0 (6.4, 7.8)
HbA1c (mmol/mol)	57.6 (50.5, 66.8)	53.4 (46.7, 61.3)
Daily insulin dose (IU/kg)	0.8 (0.6, 1.0)	0.5 (0.3, 0.7)
DBP (mmHg)	76.0 (70.0, 80.0)	80.0 (73.5, 82.5)
SBP (mmHg)	126.0 (119.0, 135.0)	135.0 (127.5, 142.5)
% Males	53.0	56.0
% Insulin therapy	100.0	46.0
% CT	7.0	23.0
% ICT	44.0	22.0
% Insulin pump	49.0	1.0
% OAD/GLP-1	4.0	68.0

[a]Missing values: BMI and BMI-SDS 13, HbA1c 62, daily insulin dose 814, SBP and DPB 115.
[b]Missing values: BMI and BMI-SDS 5, HbA1c 7, daily insulin dose 786, SBP and DPB 16.
BMI, body mass index; BMI-SDS, BMI standard deviation scores; CGM, continuous glucose monitoring; CT, conventional insulin therapy; DPB, diastolic blood pressure; ICT, intensive insulin therapy; GLP-1, glucagon-like peptide 1 receptor agonists; HbA1c, hemoglobin A1c; OAD, oral antidiabetic medication; SBP, systolic blood pressure; T1D, type 1 diabetes; T2D, type 2 diabetes.

from 11.3 events/100 PY (10.4–12.2) at baseline to 9.0 events/100 PY (8.0–10.1) with CGM use for >6 months in 2994 adult individuals with T1D. These results add to the existing literature on CGM use in adults with T1D as clinical trials did not have enough power to detect these effects owing to rare events and low sample size.[3,5,6]

BMI increased slightly in adults with T1D after CGM initiation. Similar results were also found in a pediatric cohort of T1D (2–18 years of age) from the SWEET initiative.[17] Comparing the years 2016 and 2019, the authors reported a significantly lower HbA1c, but higher BMI *z*-scores in children and adolescents with T1D switching from multiple daily injections to insulin pump with or without CGM.[17] One reason for the inverse relationship between HbA1c and BMI in T1D might be intensified diabetes treatment and management to achieve HbA1c target values while preventing severe hypoglycemia.[18,19] Nansel et al. examined the association between HbA1c and BMI in T1D and concluded that increased insulin administration might be one explanation for the inverse relationship.[18]

Compared with T1D, less research has been conducted so far on CGM use in T2D[20] and most clinical trials included individuals with insulin-treated T2D only.[21] In addition to the beneficial effects on glycemic control in adult individuals with T1D, we observed a significant reduction in mean HbA1c in T2D from 7.21% (7.17%–7.25%) at baseline to 7.00% (6.95%–7.04%) after 3–6 months of CGM use with or without insulin therapy. The observed association between CGM initiation and HbA1c reduction was strongest in individuals with a baseline HbA1c ≥8% (9.06% [8.90%–9.21%] to 7.92% [7.76%–8.08%] with CGM for >6 months). Peek and Thomas emphasized in a recently published editorial the importance to investigate potential improvements in metabolic control in adult individuals with T2D with less intensive insulin regimens.[20]

The clinical trial conducted by Martens et al.[9] recruited individuals with T2D on basal insulin without prandial insulin from primary care settings. HbA1c decreased from 9.1% to 8.0% in the CGM group and from 9.0% to 8.4% in the control group with traditional blood glucose monitoring after 8 months.[9] In addition to beneficial effects in HbA1c, a decrease in hospitalizations for severe hypoglycemia were observed in a retrospective cohort study on 5673 adult individuals with T1D and 36,080 adult individuals with T2D.[4] The proportion of people having at least one hospitalization for severe hypoglycemia within 12 months declined from 4.8% to 2.9% in T1D after CGM initiation, but increased in those without CGM initiation (3.4%–4.0%) comparing a similar time frame as in CGM initiators.[4] An even stronger decline in hypoglycemia hospitalization rates was found for individuals with T2D initiating CGM use (7.8%–3.2%), whereas rates increased in individuals without CGM initiation (1.8%–2.2%).[4]

Overall, results from clinical trials and selected observational studies reported improvements in glycemic control in adult individuals with T1D as well as T2D initiating CGM.[3] Use of CGM may be associated with improvement in treatment adherence, changes in diet, and increased physical activity through CGM readings.[20] Therefore, Peek and Thomas suggested broadening access to CGM for the adult population with type 2 diabetes, for example, through online diabetes education programs with remote training of CGM.[20,22]

Our study is limited by the fact that we could not stratify by intermittently scanned CGM and real-time CGM because we did not have information on the device for every individual in this study. However, it is estimated that ~90% of CGM in adult individuals with T1D or T2D are intermittently scanned CGM at the current stage in the countries participating in this study.[23] A further limitation is the absence of a

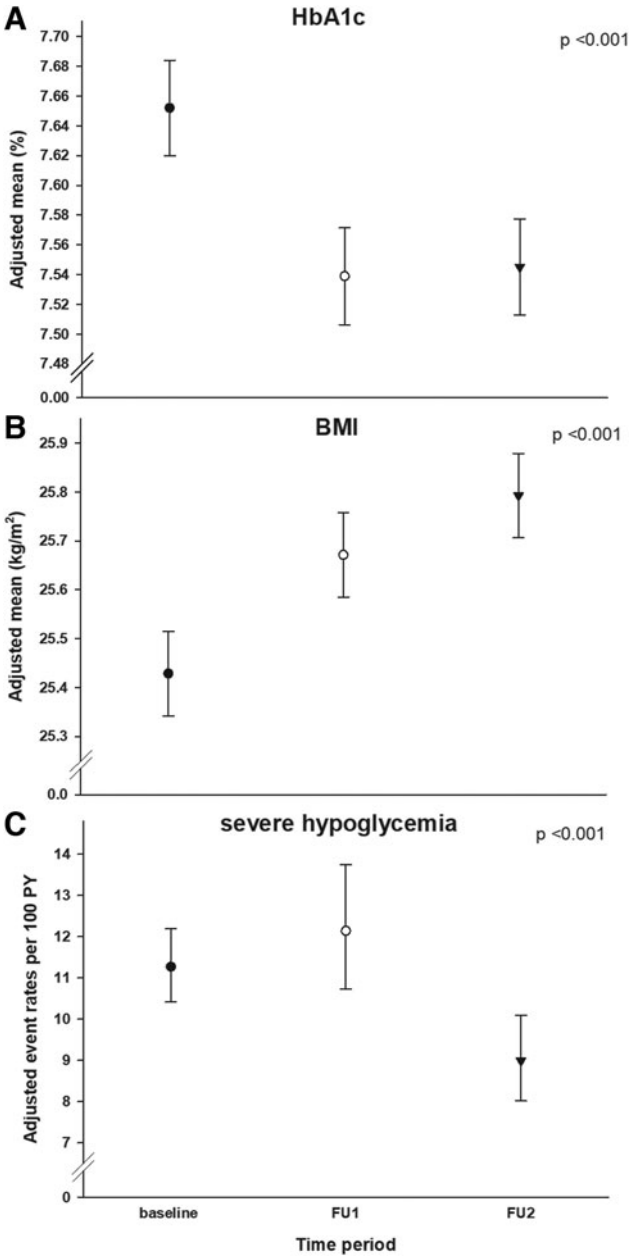

FIG. 2. Changes in adjusted means of **(A)** HbA1c, **(B)** BMI, and **(C)** event rates of severe hypoglycemia in association with CGM use in adult individuals with type 1 diabetes. FU1: follow-up period 1, CGM use for 3–6 months; FU2: follow-up period 2, CGM use for >6 months. BMI, body mass index; CGM, continuous glucose monitoring; HbA1c, hemoglobin A1c.

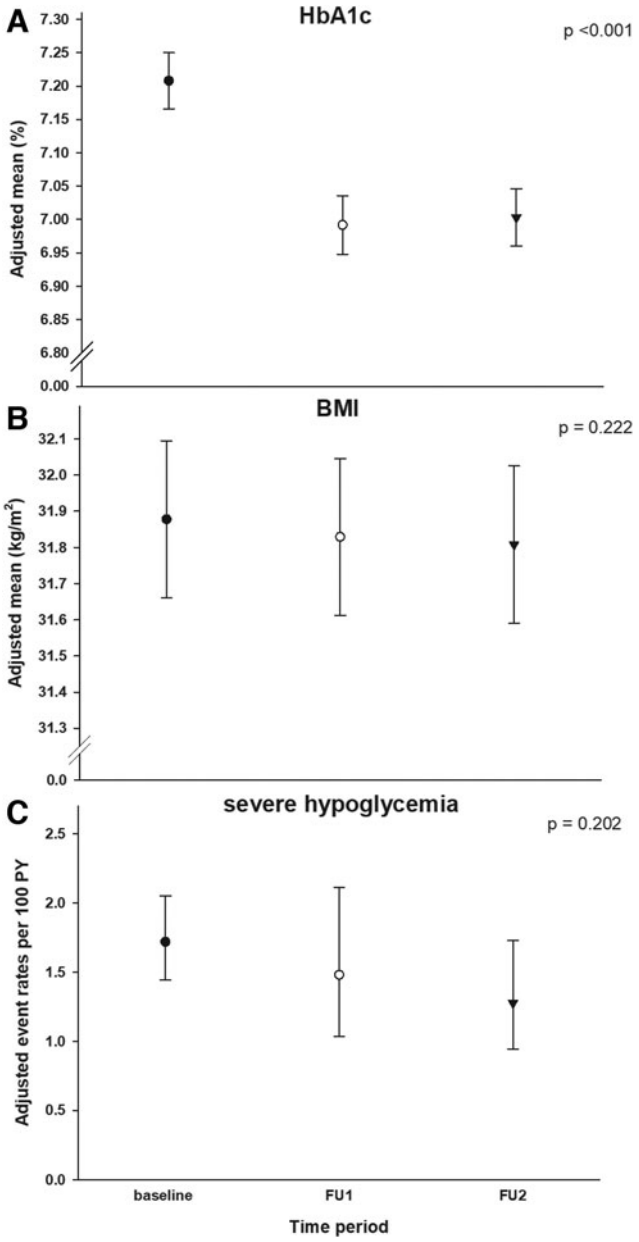

FIG. 3. Changes in adjusted means of **(A)** HbA1c, **(B)** BMI, and **(C)** event rates of severe hypoglycemia in association with CGM use in adult individuals with type 2 diabetes. FU1: follow-up period 1, CGM use for 3–6 months; FU2: follow-up period 2, CGM use for >6 months. T2D, type 2 diabetes.

control group of adults with T1D or T2D without CGM initiation. Owing to selection bias we did not match CGM users with CGM nonusers as unmeasured confounders like lifestyle factors and individual socioeconomic status might play an important role.

However, the aim of our study was to investigate changes within the individuals after CGM initiation rather than comparing CGM users with CGM nonusers. Adult individuals with diabetes treated in primary care services are underrepresented within DPV. However, the DPV registry can be regarded as representative for routine diabetes specialist care in Germany for adults with T1D or T2D. The main strength of our analysis is that we used real-world data on a large-scaled nationwide cohort of 2994 adults with T1D and 1440 adults with T2D. Therefore, our study adds to the growing body of evidence on CGM use in people with T1D and T2D as we show results from a multicenter, real-world setting.

In addition to reductions in HbA1c with CGM management, we observed a significant decrease in event rates of severe hypoglycemia in T1D and our results showed improved glycemic control with CGM use in people with T2D. We suggest strengthening patients' and physicians' readiness

toward diabetes technology in T2D, which might be achieved by remote training of CGM, and more openness of health insurance to cover cost based on proven benefits. Longer follow-up periods may give further insights into adherence to CGM, persistence of metabolic changes, as well as potentially additional beneficial effects.

Authors' Contributions

All authors contributed to the study concept and design. S.L. and R.W.H. supervised the study. S.L. analyzed the data. All authors participated in data interpretation. S.L. drafted the first version of the article. The final version of the article was reviewed and approved by all. R.W.H. is the guarantor of the study and takes full responsibility for the work, including the study design, access to data and the decision to submit and publish the article.

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Author Disclosure Statement

No competing financial interests exist.

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Supplementary Material

Supplementary Figure S1
Supplementary Figure S2
Supplementary Figure S3

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