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Changes in the utilization of blood glucose test strips among patients using intermittent-scanning continuous glucose monitoring in Germany

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Abstract

Aim: To compare the daily consumption of blood glucose test strips (BGTs) prior to and after the initiation of intermittent-scanning continuous glucose monitoring (iscCGM).

Methods: This study included 1343 adults (≥ 18 years) with type 1 (T1D) or type 2 diabetes (T2D; mean age 51.4 years; 39.1% women) from the IMS Disease Analyzer database with an initial prescription of iscCGM in Germany between January 2015 and July 2018 (index date). We compared the average daily BGTs consumption after the index date versus prior to the index date. A multivariate logistic regression model was used to investigate the association between predefined variables and the probability of no longer using BGTs after the index date.

Results: The mean (SD) daily BGTs consumption per patient decreased from 2.7 (3.0) prior to the index date to 1.4 (2.4) after the index date, and was similar in patients with T1D and those with T2D, in women and men, and across different age groups, as well in patients treated in diabetologist practices and those treated in general practices. In total, 40% of patients continued to use BGTs, and 30% used them at least once daily. Male sex and glycated haemoglobin concentration ($< 6.5\%$), as well as less frequent use of BGTs prior to the index date, were positively associated with non-use of BGTs after the index date.

Conclusion: The daily consumption of BGTs was greatly reduced after the initiation of iscCGM use in patients with diabetes. However, some patients still used BGTs in addition to iscCGM.

KEYWORDS

blood glucose test strips, CGM, diabetes

1 | INTRODUCTION

In Germany, ~7.5 million people live with diabetes.¹ Of these, 95% have type 2 (T2D) and 5% have either type 1 diabetes (T1D) or another type of diabetes.² As T1D is an autoimmune disorder and leads to complete β -cell destruction, and therefore to insulin deficiency, the only therapy suitable for T1D is administering insulin via injection, insulin pen (multiple daily injections), or insulin pump (continuous subcutaneous insulin infusion). For people with T2D, insulin is only one possibility, with lifestyle

intervention and anti-hyperglycaemic agents (eg, oral medication) being reasonable alternatives. In many cases, these anti-hyperglycaemic drugs can be very successful.^{3,4} The goal of diabetes management is always to achieve and maintain good glycaemic control. As recommended by the American Diabetes Association, a glucose target range of 3.8 to 10 mmol/L (70–180 mg/dL) should be achieved. This can, of course, be personalized as needed. The second goal is to avoid hypoglycaemia (< 3.8 mmol/L [< 70 mg/dL]) and hyperglycaemia (> 10 mmol/L [> 180 mg/dL]) as far as possible. The long-term goal of diabetes therapy is

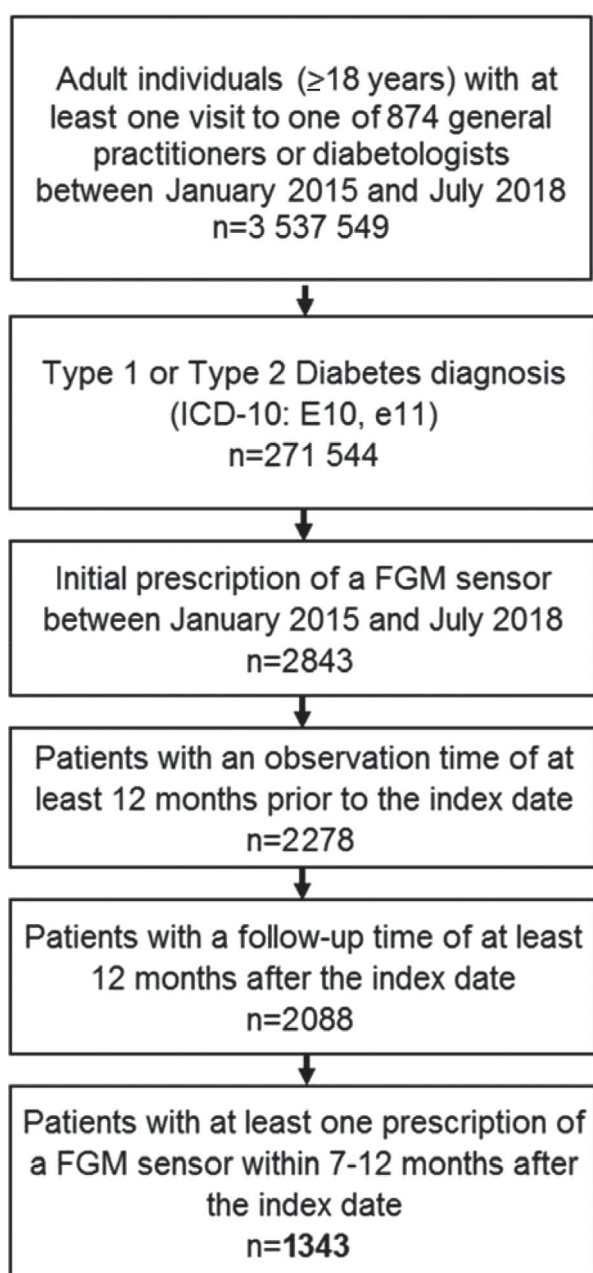


FIGURE 1 Selection of study patients

the prevention of diabetes complications, such as retinopathy, nephropathy and neuropathy.⁵⁻¹⁰

The most difficult burden in the day-to-day life of a person with diabetes is blood sugar monitoring. Many fingerpricks are needed every day to adjust the individual insulin regimen and achieve good glycaemic control. Achieving optimal glycaemic control with intensive therapy (multiple daily injections or continuous subcutaneous insulin infusion) requires frequent blood glucose monitoring (self monitoring of blood glucose [SMBG]). Unfortunately, measurement using capillary fingerpricks does not adequately prevent hypoglycaemia and hyperglycaemia. Both have an impact on quality of life, and hypoglycaemia is a particular burden for people with diabetes.¹¹ Blood glucose monitoring is very time-consuming, is painful, and must take into account many factors. Besides

TABLE 1 Basic characteristics of the study sample (N = 1343)

Variable	
Mean (SD) age, years	51.4 (16.0)
Age group, %	
18–40 years	26.3
41–50 years	18.0
51–60 years	25.5
61–70 years	18.6
>70 years	11.6
Diabetes type, %	
Type 1	48.5
Type 2	51.8
Women, %	39.1
Men, %	60.9
Practice specialty, %	
Diabetologist	81.5
General practice	18.5
Anti-hyperglycaemic therapy, %	
Insulin therapy	79.2
Insulin + OAD therapy	20.8
OAD therapy	5.4
Mean (SD) HbA1c	62.84 (15.3) mmol/mol
HbA1c concentration	
<6.5% <47.5 mmol/mol	12.4
6.5–7.4% 47.5–57.4	28.4
7.5–8.4% 57.5–68.3	28.3
≥8.5% 69.4 mmol/mol	30.9
Co-diagnoses, %	
Renal complications	24.1
Neurological complications	34.9
Peripheral vascular disease	15.6
Hypertension	44.0
Dyslipidaemia	41.2
Stroke/TIA	3.1
Myocardial infarction	4.3

Abbreviations: HbA1c, glycated haemoglobin; OAD, oral anti-hyperglycaemic drug; TIA, transient ischaemic attack.

Proportions of patients are indicated in % unless otherwise indicated. SD: standard deviation.

this, capillary blood sugar measurements are just a snapshot of the current glucose value and do not reveal where the glucose is coming from or where it is going. The intermittent-scanning continuous glucose monitoring (iscCGM) system, also called flash glucose monitoring (FGM), has been available in Germany since 2014 and is reimbursable by health insurance funds for adults and children aged 4 years and older with T1D and T2D. At the time of the present study, the only iscCGM system available in Germany was the FreeStyle Libre.

The iscCGM system is a very easy, painless and user-friendly way of monitoring glucose values without the need for blood. A small sensor is

TABLE 2 Average daily consumption of blood glucose test strips in the 6 months prior to and 6 months after the initiation of flash glucose monitoring use

Patient group	Average daily consumption of BGTS prior to the index date		Average daily consumption of BGTS after the index date		Consumption difference	
	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	P
Total	2.7 (3.0)	2.1	1.4 (2.4)	0	1.4 (3.2)	<0.001
Type 1 diabetes	2.9 (3.2)	2.2	1.6 (2.6)	0	1.3 (3.3)	<0.001
Type 2 diabetes	2.6 (2.9)	1.9	1.1 (2.2)	0	1.5 (3.1)	<0.001
Women	3.1 (3.2)	2.6	1.8 (2.7)	0	1.3 (3.4)	<0.001
Men	2.5 (2.9)	1.8	1.1 (2.2)	0	1.4 (3.1)	<0.001
Age 18–40 years	2.9 (3.2)	2.0	1.6 (2.6)	0	1.3 (3.4)	<0.001
Age 41–50 years	2.9 (3.1)	2.2	1.5 (2.6)	0	1.4 (3.2)	<0.001
Age 51–60 years	2.5 (3.0)	1.6	1.2 (2.2)	0	1.3 (3.1)	<0.001
Age 61–70 years	2.8 (2.8)	2.5	1.3 (2.4)	0	1.5 (3.0)	<0.001
Age > 70 years	2.0 (3.0)	2.4	1.2 (2.4)	0	1.6 (3.4)	<0.001
Diabetologist practice	2.9 (3.1)	2.4	1.4 (2.4)	0	1.4 (3.2)	<0.001
General practice	2.2 (2.7)	1.3	1.1 (2.4)	0	1.1 (3.2)	<0.001

Abbreviations: BGTS, blood glucose test strip; HbA1c, glycated haemoglobin; OAD, oral anti-hyperglycaemic drug; TIA, transient ischaemic attack.

inserted under the skin of one arm and remains there for 14 days. The patient can insert the sensor himself/herself and can replace it with a new sensor when the current one has expired. Current interstitial glucose values can be determined by passing the isCGM reader over the sensor. This can be done as often as the patient wishes and in any situation, and is very discreet and fast. The current value is displayed on the screen of the reader. IsCGM provides more glucose readings, leading to a glucose curve over a period of 24 hours, along with data on the rate and direction of glucose changes, assisting patients in reducing glucose variability and increasing time in range.¹²

The isCGM system needs no calibration, meaning no capillary blood tests are needed on a regular basis to keep the system functional. This can be an advantage or disadvantage, depending on the accuracy of the sensor. The CGM systems available on the German market could facilitate diabetes management, support patients in their everyday life by reducing some of their burden, and help them to achieve and maintain good glycaemic control.¹³ The self-management of blood glucose, however, has not yet been fully replaced by isCGM, or any other CGM system.

There are no published real-world data concerning the use and quantity of blood glucose test strips (BGTSs) after initiating isCGM. The aim of the present study was to compare the daily consumption of BGTSs prior to and after isCGM initiation in people with T1D or T2D.

2 | MATERIALS AND METHODS

2.1 | Database

This study was based on data from the IMS Disease Analyzer database, which compiles drug prescriptions, diagnoses and basic medical and demographic data, obtained directly and in anonymous format from computer systems used by general practitioners and specialists.¹⁴ The

database covers ~3% of all outpatient practices in Germany. Diagnoses (according to the International Classification of Diseases, 10th revision [ICD-10]), prescriptions (according to the Anatomical Therapeutic Chemical classification system), and the quality of reported data are monitored by IQVIA. The sampling methods used to select physicians' practices are appropriate for obtaining a representative database of general and specialized practices in Germany.¹⁴

2.2 | Study population

This retrospective cohort study included adults (≥ 18 years) with T1D or T2D with an initial prescription for an FGM sensor from 323 general and diabetologist practices in Germany between January 2015 and July 2018 (index date; Figure 1). This sensor is required in order to use the FGM system. Further inclusion criteria were as follows: (1) an observation time of at least 12 months prior to the index date and a follow-up time of at least 12 months after the index date; and (2) a FGM sensor prescription within 7 to 12 months after the index date to ensure that patients used the FGM sensor for at least 6 months.

2.3 | Study outcomes and covariates

The main outcome of the study was the daily consumption of BGTSs in the 0 to 183 days after the index date compared to the period of 1 to 183 days prior to the index date. The calculated daily BGTS consumption was assessed using prescription information (pack size $\times$ pack number divided by the number of days between two subsequent prescriptions). Subsequently, mean values were calculated per patient over the periods of 6 months prior to the index date and 6 months after the index date.

TABLE 3 Association between predefined variables and the probability of no longer using blood glucose test strip after the index date (logistic regression model)

Variable	Odds ratio (95% CI) ^a	P
Age 18–40 years	Reference	
Age 41–50 years	1.02 (0.72–1.44)	0.927
Age 51–60 years	1.11 (0.78–1.58)	0.551
Age 61–70 years	1.15 (0.77–1.71)	0.506
Age > 70 years	1.18 (0.72–1.92)	0.509
Type 1 diabetes	Reference	
Type 2 diabetes	1.31 (0.98–1.77)	0.071
Average daily BGTS use prior to the index date		
0–0.9	7.91 (5.83–10.71)	<0.001
1–1.9	1.34 (0.87–2.62)	0.188
2–2.9	1.36 (0.91–2.60)	0.130
≥3	Reference	
Women	Reference	
Men	1.63 (1.29–2.07)	<0.001
Diabetologist practice	0.95 (0.68–1.32)	0.757
GP practice	Reference	
OAD only therapy	6.42 (0.81–50.93)	0.078
OAD + insulin	1.00 (0.71–1.40)	0.983
Insulin-only therapy	Reference	
HbA1c <47.54 mmol/mol	1.67 (1.01–2.79)	0.045
HbA1c 47.54–57.38 mmol/mol	0.88 (0.59–1.30)	0.509
HbA1c 58.47 mmol/mol 7.5–8.4% 68.31 mmol/mol	1.10 (0.75–1.62)	0.616
HbA1c ≥69.4 mmol/mol	Reference	
Renal complications	0.79 (0.59–1.05)	0.107
Neurological complications	1.14 (0.87–1.50)	0.339
Peripheral vascular disease	0.87 (0.61–1.24)	0.441
Hypertension	1.15 (0.88–1.52)	0.310
Dyslipidaemia	0.79 (0.61–1.02)	0.065
Stroke/TIA	0.91 (0.46–1.84)	0.800
Myocardial infarction	1.15 (0.63–2.09)	0.641

Abbreviations: BGTS, blood glucose test strip; HbA1c, glycated haemoglobin; OAD, oral anti-hyperglycaemic drug; TIA, transient ischaemic attack.

^aMultivariate regression adjusted for age, sex, diabetes type, practice specialty, baseline HbA1c value, anti-hyperglycaemic therapy and comorbidities.

This analysis was performed for all patients using iscCGM, as well as separately for men and women, patients with T1D and those with T2D, the four age groups (≤40, 41–50, 51–60 and > 60 years), and patients treated by general practitioners and those treated by diabetologists. In addition, to describe the study populations, the baseline prevalence of the following diagnoses was estimated: renal complications (ICD-10: E10.2, E11.2, N18, N19); neurological complications (ICD-10: E10.4, E11.4); peripheral vascular disease (ICD-10: E10.5, E11.5, I73.9); hypertension (ICD-10: I10); dyslipidaemia (ICD-10: E78); history of stroke or

transient ischaemic attack (ICD-10: G45, I63, I64); and history of myocardial infarction (ICD-10: I21–I23, I25.2). As obesity and ophthalmological complications are not regularly documented by general practitioners, these diagnoses were not used. The proportions of patients treated with insulin alone, oral anti-hyperglycaemic drugs (OADs) alone, or insulin + OADs were recorded. Finally, the mean glycated haemoglobin (HbA1c) values at baseline and at the end of the study were estimated.

2.4 | Statistical analyses

A descriptive comparison of the average daily BGTS consumption after the index date versus prior to the index date was performed using the Wilcoxon test. To investigate the association between predefined variables and the probability of no longer using BGTSs after the index date, a multivariate logistic regression model was fitted, with no BGTS after the index date (1 = no BGTS, 0 ≥ 1 BGTSs per day) as a dependent variable, and age, sex, diabetes type, practice specialty, OAD therapy, HbA1c value, co-diagnoses, and average daily BGTS use prior to the index date as impact variables. *P* values <0.05 were taken to indicate statistical significance. Analyses were performed using SAS version 9.4.

3 | RESULTS

3.1 | Basic characteristics of the study sample

The present study included 1343 patients who had received FGM sensors. A total of 48.5% had T1D, and the remaining 51.5% had T2D. The mean (SD) age was 51.4 (16.0) years and 39.1% were women. The mean (SD) baseline HbA1c value was 62.84 mmol/mol (15.3 mmol/mol)%. An HbA1c value 6 to 12 months after initiating iscCGM use was documented for 810 of 1343 patients; the mean (SD) HbA1c was 7.7 60.66 mmol/mol (14.21 mmol/mol)%. This decreased from 62.84 mmol/mol (15.3 mmol/mol)% at baseline to 7.7 60.66 (14.21) mmol/mol 6 to 12 months after the start of iscCGM use. The difference between the mean HbA1c values after iscCGM use versus prior to iscCGM use was −2.18 mmol/mol%; however, patients with baseline HbA1c ≥58.47 mmol/mol achieved a mean change in HbA1c of −5.46 mmol/mol.

A total of 79.2% of the patients were receiving insulin therapy, 20.8% were receiving insulin + OAD therapy, and 5.4% were receiving OADs only. A total of 34.9% had a diagnosis of neurological complications, 24.1% had renal complications, and 15.6% had peripheral vascular disease (Table 1).

3.2 | Mean daily BGTS consumption in the 6 months prior to and 6 months after the initiation of FGM

Daily BGTS consumption was a non-normally distributed variable. Table 2 shows both mean and median values for daily consumption prior

to and after the index date. In total, the mean (SD) BGTS consumption decreased from 2.7 (3.0) prior to the index date to 1.4 (2.4) after the index date. This reduction in BGTS use was similar in patients with T1D and those with T2D, women and men, and across the different age groups, as well as in those treated by diabetologists and those treated in general practices (Table 2); however, 40% of patients continued to use BGTSs, and 30% used them at least once daily.

3.3 | Association between predefined variables and the probability of no longer using BGTSs after the index date

Table 3 shows the results of the multivariate regression model. Three variables were significantly associated with no longer using BGTSs after the start of FGM. Male sex (odds ratio 1.63, $P < 0.001$), HbA1c $< 6.5\%$ (odds ratio 1.67, $P = 0.045$), and use of less than one BGTS per day prior to the index date were positively associated with non-use of BGTS.

4 | DISCUSSION

This study including general and diabetologist practices in Germany, conducted between January 2015 and July 2018, resulted in two major findings. First, the mean BGTS consumption per day greatly decreased when patients began to use iscCGM systems. This reduction in BGTS use was independent of diabetes type, sex, age group, and treatment by diabetologist or general practice. Second, the proportion of patients who still used many BGTSs despite the use of iscCGM was relatively high. In addition, we found that the mean HbA1c level decreased in the iscCGM users.

In the present study, the mean daily BGTS consumption decreased from 2.7 to 1.4 per day. In the study by Tyndal et al¹⁵ in people with T1D in Scotland, a reduction from 3.8 to 0.6 test strips per day was reported. In a study in adults with well-controlled T1D by Bolinder et al¹⁶ iscCGM use reduced the time spent in a hypoglycaemic state compared with use of capillary test strips.

Glucose levels need to be closely monitored to prevent hypoglycaemia. This is necessary for both people with T1D and those with T2D, especially those taking glucose-lowering medication. People with diabetes who do not use iscCGM need to monitor their blood glucose on a regular basis using test strips. IscCGM can replace some of these SMBG measurements, either by improving metabolic control and reducing glucose variability, or by relying on the sensor glucose values, with no need to double-check using blood glucose measurements. A further study in Germany and Austria showed that a moderate decline in mean SMBG frequency between 2016 to 2017, particularly in the youngest age groups with the highest CGM rates in the study, may have been the result of the increase in non-adjunctive CGM use, requiring less routine SMBG.¹⁷

Szadkowska et al¹⁷ showed that iscCGM is accurate in children, but its accuracy depends on the glucose trend. When the glucose

level was falling, the glucose values were not as reliable, so the authors recommended a blood sugar measurement under these conditions. Another study agreed with this finding and showed that the FGM system was not as accurate during physical activity and during times of hypoglycaemia. In such situations, it is inconvenient and difficult to perform capillary blood glucose measurements for people with T1D, but very necessary, therefore, patients need to be encouraged to do so.¹⁸ There might be many patients who are still opting for capillary blood glucose testing because they doubt the accuracy of the iscCGM measures, especially in the first days of using this system.

Physiologically, there is a gap between blood glucose values and sensor glucose values when glucose is rising or falling (eg, after a meal and following an insulin injection). This is the interval the glucose needs to diffuse from the bloodstream into the interstitium. In these circumstances, the patient must perform a capillary blood test to be able to carry out therapeutic adjustments.

Being male was associated with a higher probability of not using BGTS in addition to iscCGM. Another study did not report sex-related differences in the continuing use of BGTSs while using a CGM device, although an age dependency was observed in that study.¹⁷

An HbA1c value $< 6.5\%$ was associated with not using BGTSs after the index date. This is in line with another study by Aleppo et al,¹⁹ who found that, in adults with T1D with good glycaemic control, the use of CGM without regular use of confirmatory SMBG is as safe and effective as using CGM with a confirmatory SMBG measurement.

In the present study, patients who used less than one BGTS per day prior to the index date were more likely not to use BGTSs after the index date. This finding seems to be very logical. Regular SMBG measurements are necessary in all diabetes management that uses glucose-lowering agents to achieve good glycaemic control and the burden of this is very high.²⁰ Patients who struggle with this burden before initiating iscCGM are probably more likely to replace every SMBG occasion by an iscCGM scan and to not perform any blood glucose measurements.

An additional finding of the present study was that HbA1c decreased by -2.18 mmol/mol in iscCGM users and by -5.46 mmol/mol in those with a baseline HbA1c ≥ 58.47 mmol/mol. This finding is in line with other studies that have investigated HbA1c reduction in iscCGM users. Tyndal et al¹⁵ reported a median HbA1c decrease of 0.6% in people with T1D who had a baseline HbA1c $\geq 7.5\%$. In the multicentre, randomized trial by Hermanns et al,²¹ HbA1c decreased by 0.3%. In the clinical trial by Yaron et al,²² performed in Israel in people with T2D, there was 0.8% reduction in HbA1c. Our results confirm that the use of iscCGM may improve glycaemic control in both people with T1D and those with T2D.

In general, retrospective primary care database analyses are limited by the validity and completeness of the data on which they are based. The present study is subject to several limitations, which should be noted.

First, hypoglycaemia is only rarely documented in the database, and the relationship between hypoglycaemia and the use of BGTS could not be investigated. Second, HbA1c values were only available

at baseline, and only in some patients during the time of iscCGM, for analysis of associations between iscCGM use and HbA1c reduction in the overall study population. Some studies have reported a reduction in HbA1c with the use of CGM in patients with T1D.²³⁻²⁸ Third, data on socio-economic status (eg, education and income) and lifestyle-related risk factors (eg, smoking, alcohol use and physical activity) were also lacking. Fourth, no data on diabetes duration were available. Finally, information from hospitals was not available.

The strengths of this study include the number of patients available for analysis and the use of real-world data, which allowed an unbiased exposure assessment (no recall bias).

In conclusion, the daily consumption of BGTSs was greatly reduced after the initiation of iscCGM use in patients with diabetes. However, a relatively high proportion of patients still used BGTS in addition to the iscCGM. Further longitudinal studies are needed to gain a better understanding of the relationship between the use of iscCGM and BGTS use. Future studies also need to investigate the real-world outcomes of iscCGM use, including improved HbA1c values, reduction of hypoglycaemic events, and decreased incidence of diabetes-related complications.

CONFLICTS OF INTEREST

None declared.

AUTHOR CONTRIBUTIONS

K.K. was responsible for the study concept, study design and data analysis. LVDM and KK interpreted the data. L.V.D.B. drafted the manuscript. All authors edited the drafts of the manuscript.

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