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The Impact of the FreeStyle Libre™ Flash Glucose Monitoring System on Glycemic Control in Patients with Diabetes; Observational Multicenter 15-Months Study

Saud Alsifri[1], Abdulkarim Almalki[1], Samar Alsifri[2], Naif Alsifri[3], Mohammed Moatism[1], Sahar Alsifri[4], Emad R. Issak[5]

[1]Endocrinology & Diabetes Department, Alhada Armed Forces Hospital, Taif, Saudi Arabia
[2]Medicine Department, King Fahad Armed Forces Hospital, Jeddah, Saudi Arabia
[3]Medicine Department, East Jeddah Hospital, Jeddah, Saudi Arabia
[4]King Abdulaziz University Hospital, Jeddah, Saudi Arabia
[5]Medicine Department, Asalam Center, Cairo, Egypt
Email: dr.emad.r.h.issak@gmail.com

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Abstract

Objectives: The study was to determine the impact of using the FreeStyle Libre™ flash glucose monitoring system on glycemic control and the rate of events due to diabetes in people with diabetes from different types and age groups. **Methods**: a retrospective cohort chart review study was carried out at three centers in the Taif region in the Kingdom of Saudi Arabia: The study was approved by an accredited centralized institutional review board. Paper or electronic medical records were included for individuals of any age with diabetes (type 1, type 2, gestational diabetes) managed with diet, insulin therapy, or/and oral antihyperglycemic medication and/or non-insulin injection therapy. The primary outcome measure was the laboratory HbA1c level as well as reduction. Secondary outcome measures were frequency of severe hypoglycemia, admission to hospital or ER visit related to diabetes complications, and severe hyperglycemia (DKA or HHS). **Results**: Data was analyzed from 1695 patients. The average HbA1c before using the flash glucose monitoring system was 9.60% ± 1.44% and 3 months HbA1c after using the FreeStyle Libre™ flash glucose monitoring system was 8.70% + 1.45% for a difference of −0.90% ([95% CI −0.92: −0.88]; $p < 0.0001$). The 6 months HbA1c was 8.17% + 1.53% for a difference of −1.47% ([95% CI −1.50: −1.44]; $p < 0.0001$). The 12 months HbA1c was 7.87% + 1.56% for a difference of −1.85% ([95% CI −1.88: −1.81]; $p < 0.0001$). There was a highly significant reduction in HbA1c over time after using the flash glucose monitoring system. The reduction in HbA1c is consistent among all subgroups; namely GDM on a diet,

GDM on insulin, type 1 adult, type 1 children, type 1 pregnant women, type 2 on a diet, type 2 on OAD, type 2 on basal insulin plus OAD, type 2 on multiple-dose insulin, and type 2 pregnant women, obese, non-obese, males, females, age group < 65 & age group > 65 years, (p-values < 0.001). Severe hypoglycemia 3 - 6 months before using the flash glucose monitoring system was 9.56 ± 1.73 versus 0.52 ± 0.50 in the last six months of the study (p-value < 0.001). Hyperglycemic hyperosmolar state or diabetic ketoacidosis 3 - 6 months before using the flash glucose monitoring system was 7.40 ± 2.26 versus 0.49 ± 0.50 in the last six months of the study (p-value < 0.001). Emergency room visits & hospital admissions due to diabetes complications 3 - 6 months before using the flash glucose monitoring system were 1.98 ± 0.81 versus 0.49 ± 0.50 in the last six months of the study (p-value < 0.001). **Conclusion**: The benefits of using the FreeStyle Libre™ flash glucose monitoring system are self-evident in reducing HbA1c and events due to hyperglycemia or hypoglycemia.

Keywords

FreeStyle Libre™ Flash Glucose Monitoring System, Diabetes, HbA1C, Hypoglycemia, Diabetic Ketoacidosis, Hyperglycemic Hyperosmolar State

1. Introduction

By the year 2040, the worldwide prevalence of diabetes mellitus (DM) is expected to be above 9.5%, with a total number of more than six hundred Million [1]. Also, the prevalence of DM is escalating rapidly in the Kingdom of Saudi Arabia (KSA), accompanied by the consequent over-exhaustion of the resources related to the healthcare system [2].

At the end of the second decade of the third Mellinum, the American Diabetes Association (ADA) thought up and published its first endorsement for the term time-in-range (TIR) to guide those who are responsible for diabetes management as well as individuals with DM, achieve better control of the blood glucose level by the employment of the continuous glucose monitoring (CGM) systems [3] [4].

FreeStyle Libre™ flash glucose monitoring system (FGM), a new technology for generating continuous glucose data including estimated HBA1c, TIR, time below range (TBR), and time above range (TAR), was developed for facilitating technology access to diabetes management. The essence of the flash glucose monitoring system lies in its ability to generate and analyze the dense glucose data generated by the system in a user-friendly way. The collection of the data has also been simplified to a quick scan of the sensor with the reader [5]. Hence, a panel of diabetes experts from the KSA published their consensus on using standardized reporting and TIR in the management of DM cases. They recommended the use of such technology and analyzed data by using the internationally recommended standardised CGM metrics [6].

Therefore, the rationale behind carrying out the current study was to assess

the outcomes of the utilization and introduction of the flash glucose monitoring system on glycemic control as well as the DM events (hypoglycemia, HHS, DKA).

2. Patients and Methods

The current observational retrospective cohort non-interventional single-arm chart review study was carried out at three hospitals in the Taif region in KSA: Alhada Armed Forces hospital, Prince Mansour Military Hospital, and Prince Sultan Military hospital.

The study was conformed to the 2011 Declaration of Helsinki principles and the Good Pharmacoepidemiology Practices (GPP) guidelines. The study was approved by an accredited centralized institutional review board, and informed consent was not required.

The three centers each conducted a database search for potential patients' records for two years, from June 2019 until Jun1 2021, to be included in the study. Paper or electronic medical records were included for individuals of any age with diabetes (type 1, type 2, gestational diabetes) managed with diet, insulin therapy, or/and oral antihyperglycemic medication and/or non-insulin injection therapy.

In accordance with the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, data extracted from the charts were HIPAA de-identified (anonymized) [7].

For inclusion in the analysis of this study, individuals of any age or gender, or type of diabetes should have been using the flash glucose monitoring system (Abbott Diabetes Care, Alameda, California, USA) for at least three months when the data were collected, and HbA1c measurements should be recorded for the last 3 - 6 months before using the technology.

The definition of a baseline HbA1c was a result recorded 3 - 6 months before device use commenced. If additional baseline HbA1c measurements were available, the one nearest to the index date was used. The definitions of follow-up HbA1c measurements were those of 3 months, six months, and 12 months after using the flash glucose monitoring device. All HbA1c measurements used in the analysis had been recorded in the medical records and were from a laboratory test.

In addition to baseline HbA1c concentrations, the study centers also extracted information that had been recorded in the medical records prior to initiation of the device used for age, gender, obesity, type of diabetes, duration of diabetes, insulin, oral hypoglycemic drugs (OADs), frequency of self-monitoring of blood glucose (SMBG), frequency of severe hypoglycemia, admission to hospital or emergency department visit related to diabetes and severe hyperglycemia (DKA or HHS). Also, the change in glucose metrics time in range (TIR), time below range (TBR), and time above range (TAR), as well as the frequency of scanning, were collected for the period after using the flash glucose monitoring device.

2.1. Outcomes

The primary outcome measure was the change in laboratory HbA1c level. Secondary outcome measures were assessing the frequency of severe hypoglycemia,

admission to hospital or ER visit related to diabetes complications, including severe hyperglycemia (DKA or HHS). Analysis of the primary end-point was also performed for the subgroups: age (<65 and ≥65 years), gender, obesity, and type of diabetes.

2.2. Statistical Analysis

To detect a change in HbA1c of 0.35% with a power of 80% (at $p < 0.05$), based on an SD of change in HbA1c of 1.1% [8], the sample size required is 141. To allow for subgroups analyses by type of diabetes with different treatment regimens (10 groups) more than 1410 subjects are needed.

A paired t-test was used to assess differences between HbA1c measurements before and after the patients started to use flash glucose monitoring device. Subgroups were compared using paired t-test in each group on baseline HbA1c. All statistical tests were carried out using a significance level of 95%. A value of $p < 0.05$ was considered statistically significant. SPSS software (Statistical Package for the Social Sciences, version 25.0, SSPS Inc, Chicago, IL, USA) was used for the statistical analyses. Data was presented as (mean ± SD) for continuous variables after testing for normality of all variables; all of them were normally distributed. Frequency & percentage were used for categorical variables.

3. Results

A total number of 1722 records of individuals with DM at the specified period were reviewed. Twenty-seven cases are excluded because they did not have HbA1c data before using the flash glucose monitoring device (15 records) and lost follow-up after the start of using the flash glucose monitoring device (12 records). Thus, the analysis of this study included 1695 patients where both data were available.

Description of the Included Cohort

According to the eligibility criteria, only 1695 individuals with DM were included in the analysis. Out of all included patients, 966 were females (57.00%), and 729 were males (43.00%). The mean age of cases was 43.7 ± 15.8 years. The mean duration of DM was 15.3 ± 9.8 years. About half of the patients (49.2%) were obese. Type 1 DM cases were 283 (16.70%), gestational diabetes (GDM) 160 (9.44%), and Type 2 DM cases were 1252 (73.86%) of the entire cohort. Further details about the included types of DM according to treatment regimen are shown in Table 1.

Glucose profile (HbA1c) before and after the FreeStyle Libre™ flash glucose monitoring device: the overall sample and subgroup analyses

For the primary outcome, the average HbA1c using the flash glucose monitoring device was 9.60% ± 1.44%, and three months after using the flash glucose monitoring device was 8.70% + 1.45%, for a difference of −0.90% ([95% CI −0.92: −0.88]; $p < 0.0001$). The six months HbA1c after using the flash glucose monitoring device was 8.17% + 1.53% for a difference of −1.47% ([95% CI −1.50: −1.44]; $p < 0.0001$). The 12 months HbA1c after using the flash glucose monitor-

ing device was 7.87% + 1.56% for a difference of −1.85% ([95% CI −1.88: −1.81]; p < 0.0001). There was a significant reduction in HbA1c over time after using the flash glucose monitoring device, as shown in Table 2 & Figures 1-3.

Table 1. Baseline characteristics.

Type of DM			Age years		Duration years		Gender				Obesity	
							Male		Female			
	N	%	Mean	SD	Mean	SD	N	%	N	%	N	%
All	**1695**	100%	43.7	15.8	15.3	9.8	729	43.0%	966	57.0%	834	49.2%
GDM Diet	**63**	3.7%	34.0	3.8	0.1	0.0	0	0.0%	63	100.0%	38	60.3%
GDM Insulin	**97**	5.7%	32.5	3.8	0.1	0.0	0	0.0%	97	100.0%	53	54.6%
T1 Adult	**103**	6.1%	27.9	6.6	17.6	5.8	36	35.0%	67	65.0%	55	53.4%
T1 Ped	**151**	8.9%	14.0	2.0	3.0	0.8	72	47.7%	79	52.3%	65	43.0%
T1 Preg	**29**	1.7%	25.3	1.8	18.3	1.6	0	0.0%	29	100.0%	13	44.8%
T2 BI OAD	**314**	18.5%	51.2	10.3	20.6	7.0	157	50.0%	157	50.0%	155	49.4%
T2 Diet	**54**	3.2%	32.3	5.4	1.3	0.5	28	51.9%	26	48.1%	22	40.7%
T2 MDI	**293**	17.3%	49.1	10.8	19.7	7.2	148	50.5%	145	49.5%	142	48.5%
T2 OAD (2-3)	**545**	32.2%	53.9	10.8	19.8	7.0	288	52.8%	257	47.2%	278	51.0%
T2 Preg	**46**	2.7%	31.3	2.9	4.9	0.8	0	0.0%	46	100.0%	13	28.3%

BI = basal insulin, MDI = multiple-dose insulin.

Table 2. Glucose profile and diabetes events pre & post FGM.

			Reduction		95% CI		p-value
HbA1c	Mean	SD	Mean	SD	Lower	Upper	
3 - 6 months pre FGM	9.60	1.44					
3 Months	8.70	1.45	0.90	0.42	0.88	0.92	<0.001
6 Months	8.17	1.53	1.47	0.67	1.44	1.50	<0.001
12 Months	7.87	1.56	1.85	0.70	1.81	1.88	<0.001
Severe hypoglycemia							
3 - 6 months pre FGM	9.54	1.73					
Last 6 Months of study	0.52	0.50	9.02	1.80	8.94	9.11	<0.001
Hyperglycemia							
3 - 6 months pre FGM	7.40	2.26					
Last 6 Months of study	0.49	0.50	6.91	2.33	6.80	7.02	<0.001
ER & admission							
3 - 6 months pre FGM	1.98	0.81					
Last 6 Months of study	0.49	0.50	1.49	0.94	1.44	1.53	<0.001
			Increase		95% CI		p-value
TIR post	Mean	SD	Mean	SD	Lower	Upper	
3 Months	45.62%	3.40%					
6 Months	56.93%	2.63%	11.31%	4.27%	11.10%	11.52%	<0.001
12 Months	67.90%	2.58%	22.26%	4.30%	22.05%	22.48%	<0.001

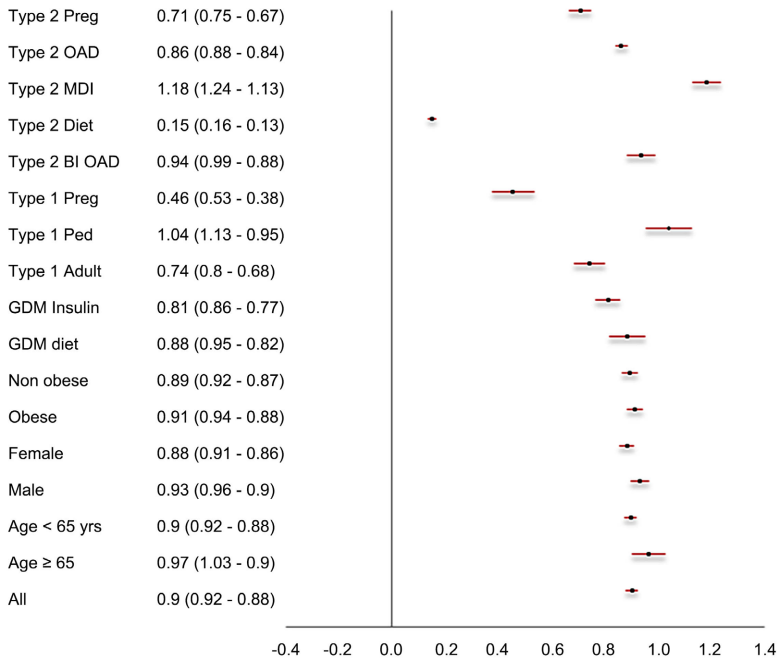

Figure 1. Reduction in HbA1c at 3 months post FGM.

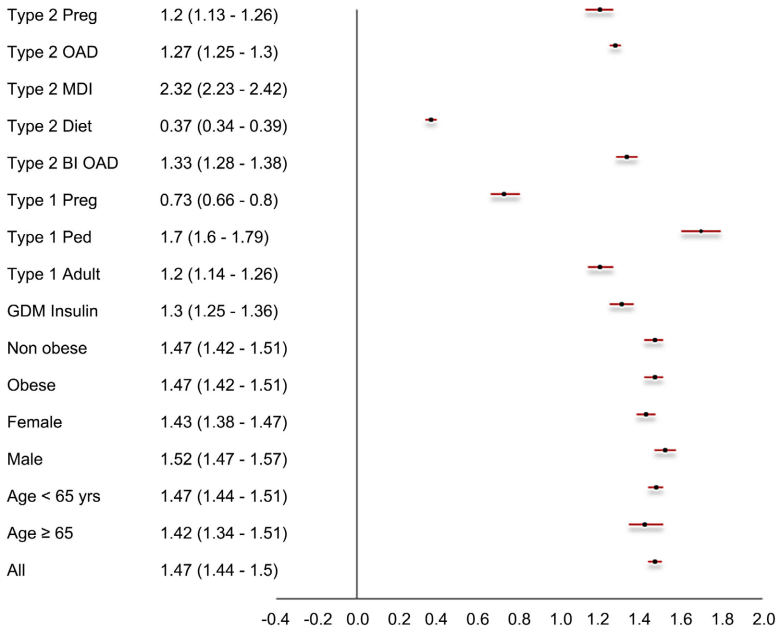

Figure 2. Reduction in HbA1c at 6 months post FGM.

The reduction in HbA1c over time is consistent among all subgroups; namely GDM on a diet, GDM on insulin, type 1 adult, type 1 children, type 1 pregnant women, type 2 on a diet, type 2 on OAD, type 2 on basal insulin plus OAD, type 2 on multiple-dose insulin, and type 2 pregnant women (p-value < 0.001), as shown in **Table 3** & **Figures 1-3**. Moreover, the reduction in HbA1c over time is consistent among all other subgroups: obese, non-obese, males, females, age group < 65 & age group ^{3}65 years, as shown in **Figures 1-3**.

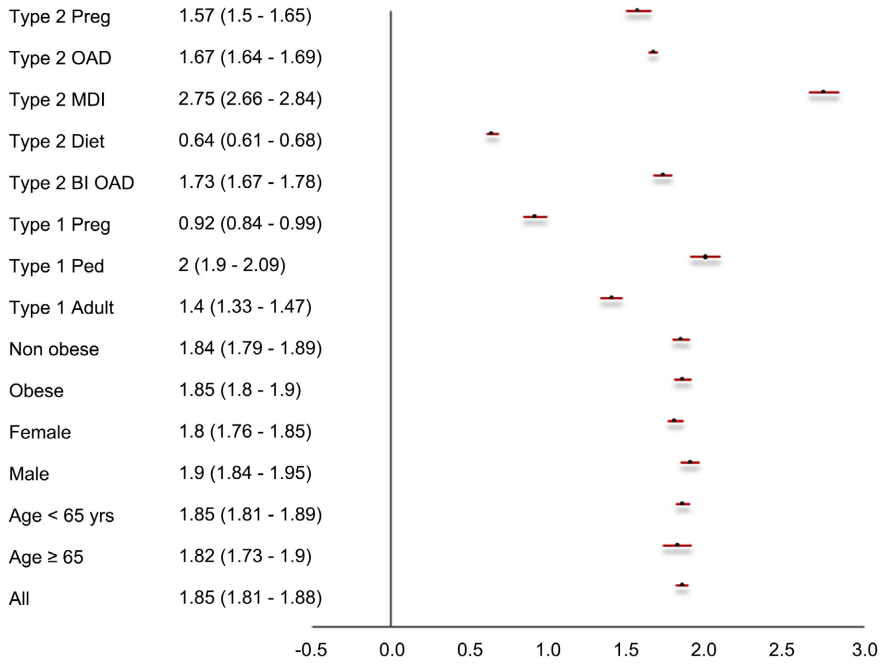

Figure 3. Reduction in HbA1c at 12 months post FGM.

Time in range (TIR) after using the flash glucose monitoring device was increased by time. For the entire cohort, it improved to 45.62% + 3.40% at three months after using the flash glucose monitoring device (p-value < 0.001). It increased to 56.93% + 2.63% at 6 months (p-value < 0.001) and to 67.9% + 2.58% by 12 months (p-value < 0.001), as shown in **Table 2**. In addition, the TIR change was consistent among all study subgroups all over the time of the study, as shown in **Table 3**.

The frequency of SMBG scanning before the FGM was 3.0 ± 1.4 per week. On the other hand, the frequency of flash glucose monitoring scanning was 22.5 ± 1.7 per day, as shown in **Table 4**.

Events related to DM before and after using FreeStyle Libre™ flash glucose monitoring device: the overall sample and subgroup analyses

Severe hypoglycemia 3 - 6 months before using the flash glucose monitoring device were 9.56 ± 1.73 versus 0.52 ± 0.50 during the last six months of the study (p-value < 0.001), as shown in **Table 2**. Severe hyperglycemia events defined as Hyperglycemic Hyperosmolar State (HHS) or diabetic ketoacidosis (DKA) 3 - 6 months before using flash glucose monitoring device was 7.40 ± 2.26 versus 0.49 ± 0.50 in the last six months of study (p-value < 0.001), as shown in **Table 2**. Emergency room visits & hospital admissions due to diabetes complications 3 - 6 months before using the flash glucose monitoring device were 1.98 ± 0.81 versus 0.49 ± 0.50 in the last six months of the study (p-value < 0.001), as shown in **Table 2**.

Moreover, the same impact seen for severe hypoglycemia events, severe hyperglycemia events & emergency room visits & hospital admissions were consistent among all the study subgroups (p-values < 0.001), as shown in **Table 5**.

Table 3. Glucose profile pre & post FGM: sub group analysis.

		HbA1c				Time in range after FGM		
		Baseline	3 m	6 m	12 m	3 m	6 m	12 m
GDM deit	Mean	8.7	7.8*			45.4%		
	SD	0.5	0.6			3.6%		
GDM insulin	Mean	8.6	7.8*	7.3*		45.5%	57.5%	
	SD	0.5	0.5	0.5		3.5%	2.5%	
Type 1 Adult	Mean	8.6	7.9*	7.4*	7.3*	45.8%	57.0%	67.7%
	SD	0.5	0.5	0.5	0.6	3.4%	2.7%	2.6%
Type 1 Ped	Mean	9.8	8.7*	8.1*	7.8*	45.8%	56.9%	67.8%
	SD	0.9	1.1	1.1	1.1	3.3%	2.6%	2.6%
Type 1 Preg	Mean	7.9	7.4*	7.2*	7.0*	46.1%	56.5%	67.2%
	SD	0.3	0.3	0.3	0.3	3.7%	2.3%	2.8%
Type 2 BI OAD	Mean	8.9	7.9*	7.5*	7.1*	45.8%	57.0%	68.0%
	SD	0.6	0.7	0.7	0.7	3.4%	2.6%	2.6%
Type 2 Diet	Mean	7.9	7.8*	7.6*	7.3*	46.5%	57.5%	68.5%
	SD	0.2	0.2	0.2	0.3	3.3%	2.6%	2.5%
Type 2 MDI	Mean	9.8	8.6*	7.5*	7.1*	45.9%	56.8%	67.9%
	SD	1.0	1.0	1.3	1.3	3.4%	2.6%	2.6%
Type 2 OAD	Mean	10.7	9.8*	9.4*	9.0*	45.2%	56.8%	67.9%
	SD	1.7	1.7	1.8	1.8	3.4%	2.6%	2.6%
Type 2 Preg	Mean	8.9	8.2*	7.7*	7.3*	45.6%	56.8%	67.9%
	SD	0.7	0.7	0.8	0.8	3.4%	2.8%	2.5%

* p-value < 0.001 comparizon to baseline HbA1c.

Table 4. Frequency of blood glucose monitoring pre and post FGM.

	SMBG per week		FGM scanning per day	
	Mean	SD	Mean	SD
All	3.0	1.4	22.5	1.7
GDM Diet	2.8	1.5	22.5	1.8
GDM Insulin	3.1	1.5	22.4	1.7
T1 Adult	3.3	1.4	22.6	1.7
T1 Ped	3.0	1.4	22.4	1.7
T1 Preg	3.1	1.3	23.1	1.4
T2 BI OAD	2.9	1.4	22.5	1.7
T2 Diet	3.3	1.3	22.5	1.6
T2 MDI	2.8	1.4	22.5	1.7
T2 OAD	3.0	1.4	22.5	1.8
T2 Preg	2.6	1.3	22.7	1.6

Table 5. Diabetes events post FGM; sub group analysis.

	Severe hypoglycemia		DKA or HHS		Admission	
	3 - 6 month pre FGM	Last 6 months	3 - 6 month pre FGM	Last 6 months	3 - 6 month pre FGM	Last 6 months
GDM deit	9.27	0.54*	7.37	0.49*	1.86	0.49*
	1.71	0.50	2.40	0.50	0.82	0.50
GDM insulin	9.42	0.44*	7.30	0.45*	1.80	0.39*
	1.60	0.50	2.08	0.50	0.80	0.49
Type 1 Adult	9.34	0.48*	7.38	0.46*	1.94	0.57*
	1.86	0.50	2.11	0.50	0.83	0.50
Type 1 Ped	9.54	0.58*	7.27	0.44*	2.03	0.50*
	1.82	0.50	2.28	0.50	0.83	0.50
Type 1 Preg	9.66	0.62*	7.62	0.59*	1.86	0.52*
	1.70	0.49	2.80	0.50	0.79	0.51
Type 2 BI OAD	9.54	0.45*	7.48	0.50*	2.00	0.53*
	1.75	0.50	2.24	0.50	0.80	0.50
Type 2 Diet	9.50	0.57*	7.57	0.56*	2.02	0.39*
	1.60	0.50	2.08	0.50	0.84	0.49
Type 2 MDI	9.67	0.55*	7.28	0.54*	1.97	0.52*
	1.67	0.50	2.26	0.50	0.81	0.50
Type 2 OAD	9.54	0.53*	7.42	0.47*	2.03	0.47*
	1.74	0.50	2.30	0.50	0.80	0.50
Type 2 Preg	9.78	0.48*	7.83	0.61*	1.80	0.43*
	1.78	0.51	2.22	0.49	0.86	0.50

* p-value < 0.001 comparison to baseline (6 month pre FGM).

4. Discussion

The flash glucose monitoring system (Abbott Diabetes Care, Alameda, California, USA) is an innovative continuous glucose monitoring (CGM) that has been adopted as an alternative or adjunct to the well-established approach the self-monitoring of blood glucose (SMBG) for patients receiving insulin therapy or other treatments [9] [10] [11] [12].

In the flash glucose monitoring system, a sensor is placed on the back of the upper arm where the sensor filament sits below the skin [13]. Every minute, the sensor monitors glucose levels in the interstitial fluid and automatically records glucose data every 15 minutes. Each sensor has 14-day battery life. To retrieve stored data, a specialized reader device or a smartphone with near-field communication capabilities can be used to scan the sensor. The monitoring device (whether smartphone application or reader) shows the current glucose level, a trend arrow that shows which way glucose levels are trending, and a graph of

glucose readings over the last eight hours [14].

The current observational multi-center study showed that, among individuals with type 1 or type 2 or gestational DM, the implementation of the flash glucose monitoring system was associated with a reduction in HbA1c, regardless of the type or the treatment used. This HbA1c benefit was consistently observed across various clinical subgroups studied: GDM on a diet, GDM on insulin, type 1 adult, type 1 children, type 1 pregnant women, type 2 on a diet, type 2 on OAD, type 2 on basal insulin plus OAD, type 2 on multiple-dose insulin, type 2 pregnant women, obese, non-obese, males, females, age group < 65 and age group ^{3}65 years. These findings are significant as they add to the growing evidence supporting the beneficial effects of using the flash glucose monitoring system on glycemic control [15] [16] [17] [18] [19].

All of the studied cases were established DM cases except those with GDM. The study included a large sample (1695) that enabled the subgroup analysis. Additionally, it used a pre-post design to mitigate potential bias and confounding.

This study's sustained reduction in HbA1c may be due to patients checking their blood glucose more frequently via the flash glucose monitoring device because it is more convenient for them. The information on their glycemic profile could have helped them adjust their treatment or behavior, either on their own or through their healthcare providers, where the latter was facilitated by remote monitoring through digital tools either the smartphone application or could-based software.

Increase in the frequency of blood glucose scanning by the device may have supported individuals with DM in identifying foods that significantly increase their blood glucose resulting in better diet selections [15].

For individuals with DM who are on insulin and can adjust insulin doses independently, more frequent scanning with the flash glucose monitoring device with its ambulatory glucose profile (AGP) may have led to more informed decision-making regarding dose adjustments resulting in improved glycemic control. These findings suggest that it has the potential to decrease HbA1c in various DM populations independently [15].

The reduction is better over time as the learning curve for individuals with DM and their healthcare providers increases. Once again, these findings could be associated with frequent healthcare provider involvement through remote monitoring. Healthcare team may have used information from the flash glucose monitoring system to facilitate the revision of medications, adjustments in medication doses, and lifestyle/behavior changes. That led to better interventions and follow-up with their healthcare team, resulting in more significant reductions in HbA1c compared to the same patients before using the flash glucose monitoring device. Ultimately, flash glucose monitoring systems should function to provide the patient and their healthcare team with more information to make better-informed decisions and prevent clinical inertia. The improvement of glycemic control was reflected in the HbA1c reduction after using the flash glucose

monitoring system, the decrease in the number of HHS or DKA events, and the number of emergency room visits & hospital admissions due to diabetes complications.

Hypoglycemia is an essential factor that must be considered when managing DM. This analysis shows that the rate of experiencing severe hypoglycemic events is reduced over time when using the flash glucose monitoring system. This finding may be attributable to patients checking their blood glucose levels more readily and frequently, leading to measures to prevent hypoglycemia. Additionally, the incidence of hypoglycemic events declines as patients continue to use their flash glucose monitoring devices. The decreasing number of hypoglycemic events supports this over time (9.54 ± 1.73 3 - 6 months before using the flash glucose monitoring system to 0.52 ± 0.50 last six months of the study). These results are consistent with current literature suggesting that the flash glucose monitoring system decreases the incidence of hypoglycemic events [20] [21] [22] [23] [24].

The current study results agree with two pivotal trials highlighting the significant contribution of flash glucose monitoring systems in DM. The IMPACT (T1DM) and REPLACE (T2DM) showed that flash glucose monitoring system could safely and successfully replace the routine SMBG and deliver remarkable clinical benefits to T1DM and T2DM patients using insulin. The multi-center randomized controlled study on adults with T2DM on intensive insulin therapy (REPLACE study) from 26 European diabetes centers was conducted to assess the safety and efficacy of new flash glucose-sensing technology to replace SMBG. The study concluded that flash glucose-sensing technology use in T2DM with intensive insulin therapy results in no difference in HbA1c change and reduced hypoglycemia, thus offering a safe, adequate replacement for SMBG. Both studies (IMPACT) and (REPLACE) showed that the flash glucose monitoring system significantly reduced all critical measures of hypoglycemia without increasing HbA1c (time in range). Hypoglycemia reduction was quick and sustained without an increase in HbA1c vs. SMBG [21] [25].

Moreover, the SELFY trial was conducted in the UK, Irish, and German children with type 1 diabetes aged 4 - 17 years old. The study showed that children with DM improved glycemic control safely and effectively with short-term flash glucose monitoring compared to SMBG in a single-arm study. However, the study was one-arm non-comparative [26].

Finally, flash glucose monitoring improved QOL and patient-reported outcome measures. Two different measurements of QOL (the Diabetes-Treatment-Satisfaction Questionnaire and the Diabetes Quality of Life survey) showed an increased overall satisfaction for flash glucose monitoring vs. taking finger-sticks. These results serve as a reminder of how much hypoglycemia impacts T2DM [21] [25].

This study is not without limitations. First, investigators were unblinded during data collection, which may have introduced investigator bias and exaggerated treatment effect sizes. Second, be retrospective in nature. However, further

research assessing cost-effectiveness is required to support this claim.

In conclusion, the benefits of implementing the flash glucose monitoring system in all types of DM of all age groups and from different treatment regimens have been self-evident in reducing HbA1c and the rate of hypoglycemia events and the rate of HHS, DKA, or hospitalizations.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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