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Impact of flash glucose monitoring on glycaemic control and quality of life in patients with type 1 diabetes: a 18-month follow-up in real life

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Highlights of the study

- Our study confirms the benefits in real-life of the FreeStyle technology in improving glycaemic control of type 1 diabetic patients, in terms of time in range and HbA_{1c}.
- Validated questionnaires indicate a better quality of life and a reduced behaviour score of hypoglyceamia when using the device.
- Hypoglycaemic events, however, were not reduced implying the need and importance of a comprehensive education leading to a correct self-management of the FreeStyle technology.

Abstract

We conducted a prospective observational study to evaluate the medium-term impact of the flash glucose monitoring system (FGM) in a type 1 diabetic population. We included 248 patients, switched from conventional blood glucose monitoring (BGM) to FGM. We evaluated glycaemic control at 2-4 (T1) and 5-11 (T2) months after initiation and at the last available visit (T3, 18±4 months). We asked patients to fill in, at T0 and T2, two questionnaires based on the Diabetes Treatment Satisfaction Questionnaire and on the Hypoglycaemia Fear Survey.

Glycaemic control improved, from 8.1± 1.3 % at T0 to 7.8±1.2 % at T1 (p<0.001) and remained unchanged after. Average number of controls increased from 3.2±1.2 BGM to 7.7± 3.9 at T1 (p<0.001). We observed a modest decrease in daily insulin doses.

We evidenced an increase in mild hypoglycaemic events, especially in well-controlled subjects, but no increase of severe events. Satisfaction score improved from 30.5±7.7 points to 38.3±5.1 points (p=0.018), was correlated with the reduction in HbA1c and was higher in less controlled patients at inclusion. "Behaviour" score regarding hypoglycaemias decrease from 5.7±4.1 to 4.4±3.6 points (p<0.001).

In conclusion, this 18-months study trial indicates that using the FGM technology in patients with T1D may improve glycaemic control, in real-life conditions, especially in less controlled patients. FGM was associated with an increase of patients' satisfaction regarding treatment. Hypoglycaemic events, however, were not reduced in frequency. Therefore, the need for an educational team and a structure program in the management of this new technology remains mandatory.

Introduction

A new generation of non-invasive continuous interstitial glucose monitoring is currently successfully used for patients with type 1 (T1D) and type 2 (T2D) diabetes (1-5). The flash glucose monitoring (FGM) system (FreeStyle Libre®; Abbott Diabetes Care, Alameda, CA, USA) was the first available device in Belgium in 2016.

The FGM is composed of a small, single use (14 days) factory-calibrated sensor that continuously measures interstitial glucose levels. Real time glucose values can be obtained every 15 minutes (6). The clinical interest for this innovating approach is major since interstitial results were found reliable and accurate when compared with capillary measurements (BGM), without being affected by patient's characteristics, as shown by Bailey *et al*. (7).

In terms of glycaemic control, randomized trials have evidenced, when compared with BGM, an increase in glucose testing frequency and a reduction in hypoglycaemic events, without modification of HbA_{1c} levels (1, 2). In contrast, in observational studies, FGM was associated with an amelioration of glycaemic control (3, 5, 8, 9) and, in a real-world setting, with reduction of HbA_{1c} (4).

Moreover, importantly, the quality of life of T1D and T2D individuals using FGM, evaluated by specific questionnaires, was clearly improved (1, 9-11).

In this context, we conducted a prospective monocentric study in order to evaluate the medium-term impact of FGM introduction in patients followed in our centre. The first objective was to analyse the evolution of glycaemic control, after implementation of FGM. We also aimed to evaluate the effects of FGM on the number of daily glucose controls and hypoglycaemic events. Patients' satisfaction was evaluated by two questionnaires targeting quality of life and behaviour/fear of hypoglycaemias.

Patients and methods

The present trial was conducted in the University Hospital Saint-Luc in Brussels, Belgium. We included all consecutive adult diabetic subjects who were switched from BGM to FGM between November 2016 and August 2017. Baseline information (T0) included demographic data and clinical characteristics, as well as insulin doses, number of daily blood glucose results using BGM and hypoglycaemic events (defined by a value < 70 mg/dl) during the two months period before T0. The latter parameters were reevaluated 2-4 (T1) and 5-11 (T2) months after initiation of FGM. In addition, after the main study period (T0-T2), we recorded the last available HbA_{1c} value in the file (measured by HPLC) as well as the number of daily scans (18 ± 4 months) (T3). The data from FGM

system were downloaded from the Abbott software for the two months period prior to each visit (T1-T3). Patients were also asked to fill in two validated questionnaires at baseline and T2. The first questionnaire, based on the Diabetes Treatment Satisfaction Questionnaire (DTSQ), evaluated changes from baseline in satisfaction of diabetes regimen (11). It is composed of eight items with answers ranging from very satisfied (6/6) to very dissatisfied (0/6) (maximum score 48). The second questionnaire (Hypoglycaemia Fear Survey, HFS) evaluated patient's "behaviour" regarding hypoglycaemic events (6 items; maximum score 24 meaning a high adaptation in daily life to limit the occurrence of hypoglycaemias) and "worry" regarding such events (6 items; maximum score 24 meaning a high fear of hypoglycaemias) (12).

Insulin titration algorithms in this trial were left to the appreciation of the practitioner. Due to the observational design of this study, data could be missing at T1 and/or T2. Thus, at T1, data were collected from 172 (67 % of the initial cohort) and at T2, for 222 patients (86.4 %). All patients signed informed consent. We obtained the approval of the Ethic Committee of UCL (2016/13DEC/540-B403201630591).

Statistical analysis

Data were analysed using IBM SPSS Statistics version 24.0 (SPSS Inc., Chicago, IL).

We calculated delta HbA_{1c} between T0 and T1 and between T0 and T2 in order to have a positive value in case of glycaemic control improvement during follow-up. Delta satisfaction score were also calculated between T2 and T0, in order to have a positive value in case of satisfaction improvement. For descriptive purposes, mean, standard deviation, median, minimum and maximum values are represented for continuous variables, and number and percentages are presented for categorical variables. Differences between groups were analysed by ANOVA test. We used a student t-paired test to evaluate the effect of FGM on different parameters. Chi-squared tests were used for comparisons between categorical parameters. Pearson correlation coefficients were calculated to assess relationships between different variables. Factors associated with HbA_{1c} and with questionnaire responses at inclusion, as well as predictive factors of change of those parameters during follow-up were analysed by a multiple logistic regression analysis.

Results

We recruited 257 diabetic patients. Nine were excluded for insufficient data. The full analysis set at T0 included 248 patients, 98 % had T1D and 2 % diabetes secondary to pancreatectomy. Patients' clinical and biological characteristics at baseline are indicated in **Table 1**. Age was 45 ± 16 years (mean ± SD). HbA_{1c} was 8.1 ± 1.3 %; HbA_{1c} values lower than 7.0 % and 7.5 % were observed in 19

and 35 % of patients, respectively. During the two months prior to T0, the number of daily BGM controls was 3.2 ± 1.2; mean capillary glycaemia was 177 ± 41 mg/dl and patients reported 13 ± 14 hypoglycaemic events.

HbA_{1c} decreased to 7.8 ± 1.2 % at T1 (*p<0.001 vs.* T0) and 7.9 ± 1.2 % at T2 (*p=0.03 vs*. T0, NS *vs*. T1), respectively (**Table 2**). At T2, 22 % of patients had an HbA_{1c} level ≤ 7.0 % and 39 % ≤ 7.5 % (*p<0.001 vs.* T0). At T3, HbA_{1c} was 7.9 ± 1.2 % (*p<0.001 vs*. T0; NS *vs*. T1 and T2). As shown in **Figure 1**, there was, at T2, a modest HbA_{1c} increase in a subgroup of individuals with a baseline HbA_{1c} ≤ 7.2 % (first quartile; Q1). On the contrary, HbA_{1c} levels were significantly reduced overtime in the other subgroups (Q2-Q4) (*p<0.001*). An excellent correlation was evidenced between HbA_{1c} results and FGM estimated value (r: 0.818, *p<0.001*). The average number of controls per day increased to 7.7 ± 3.9 at T1 (*p<0.001*) and 7.7 ± 4.4 scans at T2 (NS *vs*. T1) (**Table 2**). Interstitial glucose at T1 and T2 remained unchanged (**Table 2**). Time spent in glycaemic targets (70-180 mg/dl) was 47 ± 14 % at T1 and 46 ± 14 % at T2 (NS) and was higher in the subgroup of patients with a better glycaemic control at inclusion. The number of daily scan with FGM was negatively correlated with HbA_{1c} (r: -0.395, *p<0.001*) (**Figure 2A**) as well as with time in range (r: -0.619, *p<0.001*) (**Figure 2B**).

As indicated in **Table 2**, there was a modest decrease in the total daily insulin doses during the study period, from 0.70 ± 0.26 to 0.68 ± 0.24 units/kg/day (*p=0.04*). BMI remained unchanged.

No increase in episodes of severe hypoglycaemias (requiring third-party assistance and/or injection of glucagon) was recorded. As far as mild hypoglycaemic events are concerned, we observed, during the 2 months prior to visits), an increase from 13 ± 14 at T0 to 48 ± 31 at T1 (*p<0.001*), and 53 ± 33 episodes/patient at T2 (*p<0.001 vs*. T0, *p=0.038 vs*. T1) (**Table 2**). As expected, the frequency of hypoglycemic events was significantly higher at T1 (*p=0.006*) and T2 (*p<0.001*) in Q1 HbA_{1c} subjects (≤ 7.2 % at inclusion). Moreover, there was a correlation between the number of hypoglycaemic events and the HbA_{1c} value at inclusion (r: -0.318, *p<0.001*), T1 (r: -0.273, *p=0.003*) and at T2 (r: -0.596, *p<0.001*).

At baseline, the satisfaction score regarding treatment and glucose monitoring was 30.5 ± 7.7 points (**Table 2**). A negative correlation with HbA_{1c} was noticed (r: -0.366, *p<0.001*). At T2, we observed a 20 % increase in satisfaction, to 38.3 ± 5.1 points (*p=0.018*). The change in score [T2-T0] was significantly correlated with the reduction in HbA_{1c} (r: 0.249, *p<0.001*) and was higher in patients aged less (*vs*. more) than 43 years (*p<0.001*) and in patients with a bad glycaemic control (Q3 and Q4 *vs.* Q1 and Q2) at inclusion (*p<0.001*).

The "behaviour" score regarding hypoglycaemias decrease significantly from 5.7 ± 4.1 to 4.4 ± 3.6 points (*p<0.001*) (**Table 2**). This means, on a practical point of view, a lower behavioural avoidance to prevent hypoglycaemia. A small reduction in the "worry" score did not reach the level of significance. It is of interest to mention that those questionnaires were completed by all patients, including the 8 participants who drop out of the study, mainly due to recurrent premature detachment of the sensor or skin reactions. In 2 patients, FSL was interrupted due to important variations between results obtained by FSL and by simultaneous BGM.

Discussion

Presently, there is an agreement that FGM achieves better assessment of glucose homeostasis *vs.* BGM, in particular in patients with T1D, as shown by randomized and observational studies (1, 5, 13). Such a technology offers indeed a unique opportunity to capture the upward and downward glucose fluctuations and to detect silent hypoglycaemic episodes (1). It also facilitates the adjustment of insulin doses, which could be potentially limited by the reluctance of many patients to perform multiple BGM.

Our prospective study shows that the use of FGM is associated with a significant reduction in HbA_{1c} levels over a course of 18 months. At T2, nearly 40 % of patients had an HbA_{1c} level lower than 7.5 %. Moreover, the percentage of time in the target was close to 50 %. However, in phase with the data of Dover *et al*. (13) and Paris *et al.* (8) we observed that such an improvement in glycaemic control was not observed in T1D subjects with optimized levels of HbA_{1c} at inclusion (Q1, ≤ 7.2 %). Similarly, Bolinder *et al*., in a cohort of well controlled T1D patients (HbA_{1c} ≤ 7.5 %) did not observed a change in HbA_{1c} results (1). Less controlled patients seemed to be those who benefit the most of this technology. It is of interest to mention that, extending data from other studies, we evidenced a relationship between HbA_{1c}, time in the target and number of daily scans (4). The amelioration in glycaemic control was however associated with an increase in hypoglycaemic episodes, despite a small reduction in insulin doses when compared with baseline. Mild hypoglycaemic events were more common, as expected, in well-controlled patients at baseline and during study follow-up. Comparable results in this field were reported by Paris *et al*. (8). Other studies, however, did not report such an increase in hypoglycaemias with FGM (1, 2, 9, 13). This increase in the number of events in our study could be due to numerous silent events, which were unnoticed during conventional BGM. On the other hand, the behavioural avoidance to prevent hypoglycaemia was lower, as indicated by the questionnaires, with as a potential consequence, a reduced maintenance of high blood glucose levels. Additional insulin injections linked to glycaemic excursions revealed by the FGM could also influence our observation. Some reports also indicated a trend of overestimation

of hypoglycaemia by FGM and a certain lack of accuracy for low glucose values (10, 14). Finally, we did not ask our patients to cross-check BGM in order to confirm the FGM data, in particular hypoglycaemias.

We evidenced a significant increase in the number of daily checks, from 3.2 conventional BGM to 7.7 scans after 3 months of FGM use. This observation is in phase with all available randomized and observational studies, in which authors evidenced a rapid abandonment of BGM in patients on FSL (1-2, 5, 8-10, 15). In agreement with Dunn *et al*., we observed a negative correlation between HbA_{1c} and the number of daily self-checks, confirming the relation between the frequency of scanning and the overall glucose control (4). The performance of the technique depends therefore on how often it is used, a concept already described with BGM (16).

It is of interest to highlight that, in phase with other studies (1, 9-11, 15, 17), FGM was linked with an improvement in treatment satisfaction, which was high at T2 (38 on a scale of 48), in particular in younger patients and in those with the highest reduction in HbA_{1c} values during the study period. This study also evaluates by a questionnaire the "behaviour" and the "fear" of hypoglycamias. As already mentioned, a reduction in the behaviour score was observed at T2, meaning that subjects could adapt less their daily life attitude to prevent hypoglycaemia. On the other hand, in phase with the IMPACT study (1), the fear of hypoglycaemia remained unchanged, but was already low at inclusion. The absence of real-time alarm could partly account for this observation. Moreover, the study period could be too short to influence this fear already present for years. It is, however, of interest to mention that Al Hayek *et al.,* in a young population ranged from 13 to 19 years with a shorter duration of diabetes, evidenced a reduction in the fear of hypoglycaemia after only 3 months of FGM use (18).

Reported side effects include mainly recurrent premature detachment of the sensor and skin reactions, as previously reported (19).

This study has limitations that deserve consideration, in particular the absence of control group. However, our follow-up data with FGM were rigorously compared with a 2 months duration based period with BGM. Also, during the present study, there were no systematic cross-checks between FGM and BGM results in order to confirm results, neither measures of glycaemic variability by itself, as time in range index is currently considered a more performant marker of glycaemic control.

In conclusion, this 18-months study trial indicates that using the FGM technology in patients with T1D may lead, beyond the comfort, to improved glycaemic control, in real-life conditions, especially in less controlled patients. FGM was associated with an increase of patients' satisfaction regarding

treatment. Hypoglycaemic events, however, were not reduced in frequency. Therefore, the need for an educational team and a structure program in the management of this new technology remains mandatory.

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Table 1: Baseline characteristics of the patients

n		248
Age	years	45 ± 16* Median: 43
Sex	M/F (%)	54 / 46
Duration of diabetes	years	20 ± 13
BMI	kg/m²	25.5 ± 4.6
Type 1 diabetes	n (%)	243 (98)
Chronic complications	%	44
- retinopathy	%	37
- nephropathy	%	18
- peripheral polyneuropathy	%	17
- autonomous neuropathy	%	6
- coronary macroangiopathy	%	7
- peripheral macroangiopathy	%	6
Insulin treatment		
- multiple daily injections	%	90
- continuous subcutaneous insulin infusion	%	10
Insulin		
- total daily dose	units	0.70 ± 0.26
- basal daily dose	units	0.34 ± 0.15
HbA_{1c}	% (mmol/mol)	8.1 ± 1.3 (65 ± 15)
Mean glycaemia using BGM°	mg/dl	177 ± 41
BGM frequency°	n/day	3.2 ± 1.6
Hypoglycaemic events°	n/2 months/patient	13 ± 14 median: 8.0 (0-81)

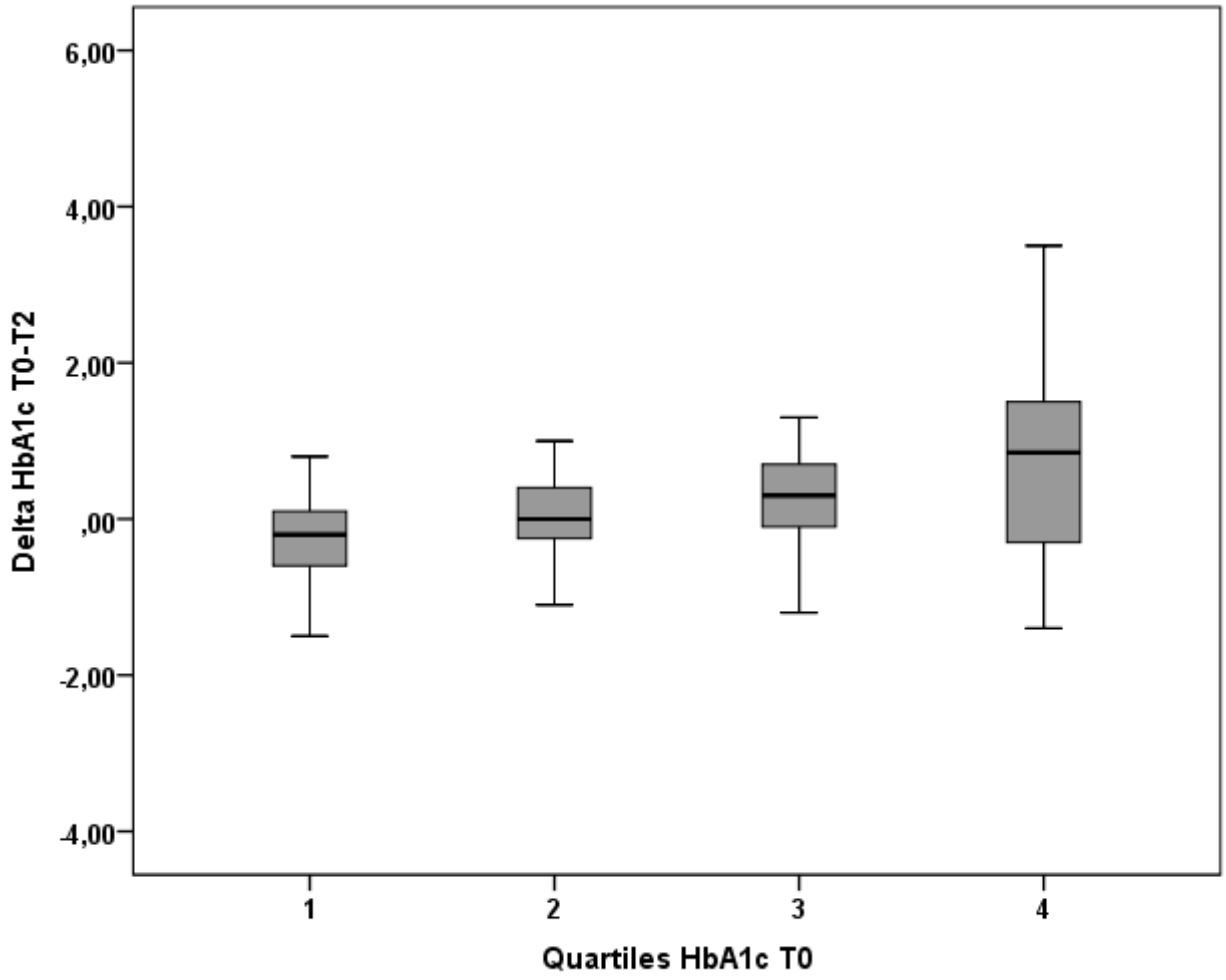
Results are presented as mean (SD), median, n (%).
BMI: body mass index. BGM: blood glucose monitoring.
° in the 2 months period before the inclusion.

Table 2: Evolution of clinical parameters and responses to questionnaires during follow-up

		T0	T1	T2	*p* T1-T0	*p* T2-T0	*p* T2-T1
HbA_{1c}	%	8.1 ± 1.3	7.8 ± 1.2	7.9 ± 1.2	*<0.001*	*0.03*	NS
BMI	kg/m²	25.5 ± 4.6		26.0 ± 4.8		NS	
Mean glucose value*	mg/dl	177 ± 41°	175 ± 32¶	176 ± 33¶	*NS*	NS	NS
Glucose monitoring frequency*	n/day	3.2 ± 1.6	7.7 ± 3.9	7.7 ± 4.4	*<0.001*	*0.01*	NS
Insulin							
- total daily dose	U/kg/day	0.70 ± 0.26		0.68 ± 0.24		*0.04*	
- basal daily dose	U/kg/day	0.34 ± 0.15		0.32 ± 0.14		*0.05*	
Hypoglycaemic events*	n/2 months /patient	13 ± 14	48 ± 31	53 ± 33	*<0.001*	*<0.001*	*0.038*
Time spent in glycaemic targets*	%		47 ± 14	46 ± 14			NS
Satisfaction score	/48	30.5 ± 7.7		38.3 ± 5.1		*0.018*	
Hypoglycaemia behaviour score	/24	5.7 ± 4.1		4.4 ± 3.6		*<0.001*	
Hypoglycaemia fear score	/24	7.2 ± 4.8		6.6 ± 5.4		*0.15*	

Results are presented as mean (SD).
T0: inclusion; T1: after 2-4 months, T2: after 5-11 months.
*in the 2 months period before the visit.
° blood glucose monitoring; ¶interstitial glucose value.

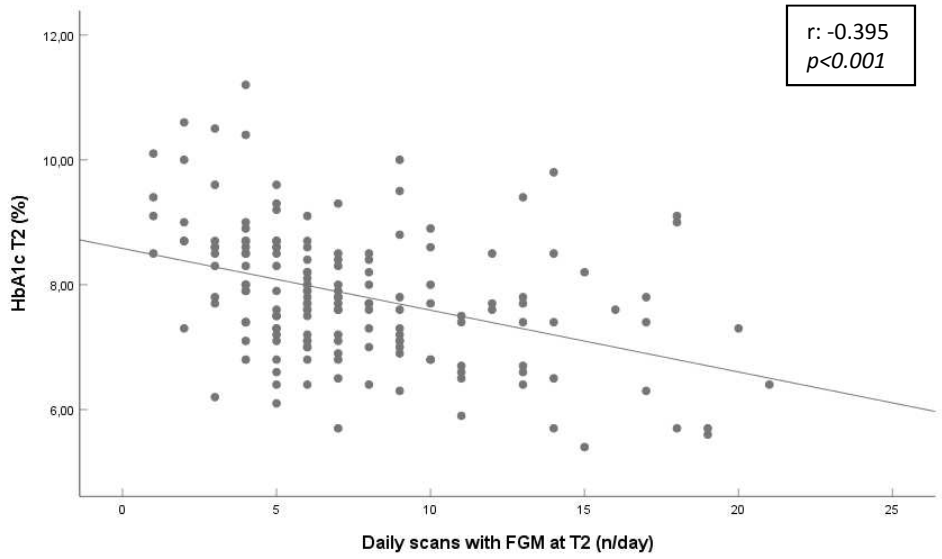
Figure 1: **Delta HbA_{1c} between T2 and T0 regarding HbA_{1c} quartiles at inclusion**



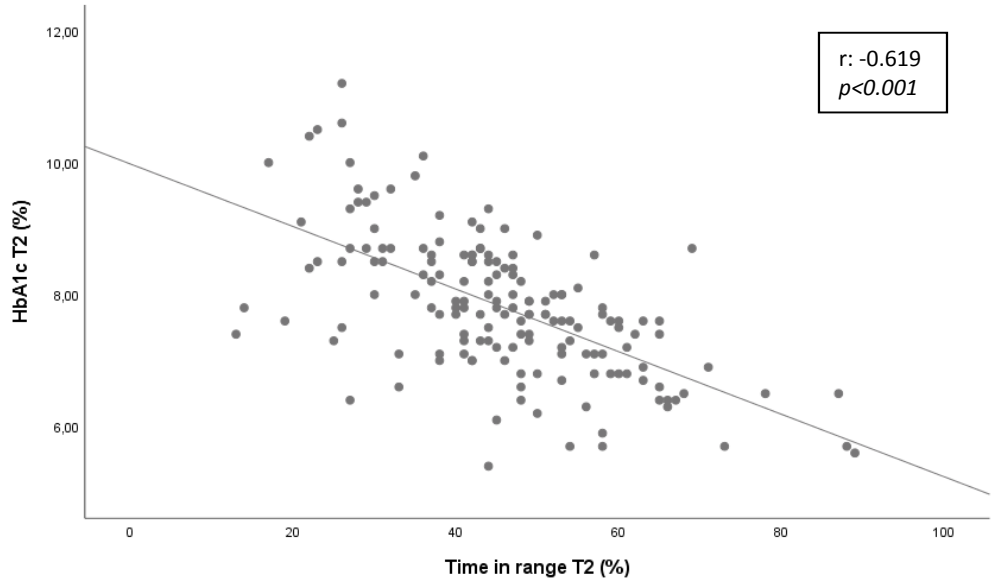
Results presented in median, interquartile ranges, P5-P95.
Delta HbA_{1c}: HbA_{1c} change between T0 and T2; Quartiles of HbA_{1c} at inclusion: Q1 ≤ 7.2 %; Q2 > 7.2 ≤ 8.0 %; Q3 > 8.0 ≤ 8.8 %; Q4 > 8.8 %.
Q1 *vs*. Q2: *p=0.013*; Q1 *vs*. Q3: *p<0.001*; Q1 *vs*. Q4: *p<0.001*; Q2 *vs*. Q4: *p<0.001*; Q3 *vs*. Q4: *p<0.001.*

Figure 2:

A: Correlation between HbA_{1c} and number of daily scans at T2



B: Correlation between time in range and number of daily scans at T2



The authors have no conflicts of interest in the field of this study.