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# Impact of flash glucose monitoring on quality of life and glycaemic control parameters in adults with type 1 diabetes mellitus★☆

**Rebeca Jiménez-Sahagún[a,b,*], Emilia Gómez Hoyos[a,b], Gonzalo Díaz Soto[a,b], María de la O Nieto de la Marca[a], Marta Sánchez Ibáñez[a], Sofía del Amo Simón[a], Beatriz Torres Torres[a,b], Juan José López Gómez[a,b], Esther Delgado García[a,b], Ana Ortolá Buigues[a,b], Daniel de Luis Román[a,b]**

[a] *Servicio de Endocrinología y Nutrición, Hospital Clínico Universitario de Valladolid, Valladolid, Spain*
[b] *Centro de Investigación en Endocrinología y Nutrición (IENVA), Facultad de Medicina, Valladolid, Spain*

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**KEYWORDS**
Flash glucose monitoring;
Type 1 diabetes mellitus;
Quality of life;
Glycaemic control;
Blood glucose self-monitoring

**Abstract**
*Introduction:* Flash glucose monitoring (FGM) improves some glycaemic control variables and quality of life parameters.
*Objective:* Our aim was to evaluate the quality of life and glycaemic control parameters after initiating FGM in patients with type 1 diabetes (DM1) in clinical practice.
*Material and methods:* A prospective observational study in DM1 patients that started using FGM between June 2019 and April 2020. We analysed their scores on the Diabetes Quality of Life (DQOL) questionnaire, Diabetes Distress Scale (DDS), Diabetes Treatment Satisfaction Questionnaire (DTSQ) and glycaemic control parameters at baseline and 3 months after the FGM onset.
*Results:* We recruited 114 patients, 56% male, mean age 37.2 (standard deviation, SD 12.4), with 18.7 (SD 11.5) years of DM1, 24.6% of which used continuous subcutaneous insulin infusion. Differences were observed (baseline vs. 3 months) in the DTSQ score (22 [15.5-27] vs. 25 [22-28], $P < 0.001$) and in the DQOL score (88 [74-104] vs. 84 [70-101], $P = 0.017$) but not in the DDS score. HbA1c was 7.8% (SD 1.3) vs. 7.4% (SD 1.1) ($P < 0.001$), without improvement in other glycaemic control variables, except for the mean number of hypoglycaemic events/14 days: 14 (SD 9) at baseline vs. 11.5 (SD 7) at 3 months ($P < 0.001$).

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* Corresponding author.
*E-mail address:* rebebel9@gmail.com (R. Jiménez-Sahagún).

*Conclusions:* The initiation of FGM, combined with a structured educational programme, was associated with improvement in quality of life and patient satisfaction in DM1 patients. An improvement in HbA1c and a reduction in the number of hypoglycaemia events was observed, but not in the rest of glycaemic control parameters.


**PALABRAS CLAVE**
Monitorización de *flash* de glucosa;
Diabetes mellitus de tipo 1;
Calidad de vida;
Control glucémico;
Automonitorización de glucemia

**Impacto del inicio de la monitorización *flash* de glucosa en la calidad de vida y en los parámetros de control glucémico de pacientes adultos con diabetes tipo 1**

**Resumen**
*Introducción:* La monitorización *flash* de glucosa (MFG) mejora algunas variables de control glucémico y parámetros de calidad de vida.
*Objetivo:* Evaluar la calidad de vida y el control glucémico tras el inicio de MFG en pacientes con DM1 en la práctica clínica.
*Material y métodos:* Estudio observacional prospectivo en pacientes con DM1 que iniciaron MFG (de junio de 2019 a abril de 2020). Se evaluaron las puntuaciones de: cuestionario de calidad de vida específico para la diabetes mellitus (EsDQOL), escala de distrés relacionado con la diabetes (EsDDS), *Diabetes Treatment Satisfaction Questionnaire* (EsDTSQ) y variables de control glucémico al inicio y a los 3 meses de MFG.
*Resultados:* Se seleccionó a 114 pacientes, el 56% varones, con una edad media de 37,2 años (DE 12,4) con 18,7 años (DE 11,5) de DM1. El 24,6% tenía infusión subcutánea contínua de insulina. Se observaron diferencias (basalmente vs. 3 meses) en la puntuación de EsDTSQ (22 [15,5-27] vs. 25 [22-28]; $p < 0,001$) y en el EsDQOL (88 [74-104] vs. 84 [70-101]; $p = 0,017$), pero no en la EsDDS. La HbA1c fue 7,8% (1,3) vs. 7,4% (1,1); $p < 0,001$), sin mejoría en otras variables de control glucémico, salvo el número medio de eventos de hipoglucemia/14 días: 14 (DE 9) al inicio frente a 11,5 (DE 7) a los 3 meses ($p < 0,001$).
*Conclusiones:* El inicio de la MFG, asociado a un programa educativo estructurado, en pacientes adultos con DM1, se asoció a mejoría en la calidad de vida y a mayor satisfacción con el tratamiento de la diabetes. Se observó mejoría en la HbA1c y menor número de eventos de hipoglucemia, pero no hubo efectos en el resto de los parámetros glucémicos.


## Introduction

The widespread use of flash glucose monitoring (GM) has been a milestone in the history of diabetes, especially for patients with type 1 diabetes mellitus (DM1). Flash GM is an alternative to continuous glucose monitoring because of its lower cost, no need for calibration and sufficient degree of accuracy.[1] It has also shown improvement in metabolic control.[2–10] However, less is known about its actual benefits in terms of patients' quality of life.[11] The only available evidence comes from sub-analyses of randomised clinical trials and a few observational studies. Patient satisfaction with the treatment and its impact on the psychosocial sphere have not been evaluated in all the studies.

The variability of the scales used in the studies makes them difficult to compare. With one of the most widely used scales, the Diabetes Treatment Satisfaction Questionnaire (DTSQ), satisfaction with flash GM was reported in both randomised clinical trials[12] and observational studies.[13,14] However, with the specific quality of life questionnaire for diabetes mellitus (Diabetes Quality of Life, DQOL), no improvement in quality of life was found in adult patients with DM1, in either clinical trials or observational studies.[12,15] Another highly relevant factor, the stress associated with diabetes, can be assessed using the Diabetes Distress Screening Scale (DDS), and favourable results have been reported with this scale.[2]

Flash GM has shown benefits in terms of metabolic control in adult patients with DM1. In randomised clinical trials, compared to self-monitoring of capillary blood glucose, flash GM showed significant improvement in the number of hypoglycaemic events and the time spent in hypoglycaemia, although it did not lead to changes in HbA1c.[12] In clinical practice, however, a decrease in HbA1c has been reported in several studies,[2,4,16] especially in subjects with higher baseline values,[3] patients with higher scan rates[4,16] and patients who had received structured diabetes education.[17] There is also disagreement between different studies with regard to blood glucose variability parameters, time in range (TIR), time in hyperglycaemia and time in hypoglycaemia.[1] In a recent real-life study, improvement was reported in all of these values, proportional to the number of daily scans and significant from 16 scans/day.[16]

We decided to conduct this study because of the lack of evidence on the impact of flash GM on the quality of life parameters of adult patients with DM1 and the inconsistent results from different studies on the effect of flash GM on certain blood glucose control variables. Our aim was to evaluate quality of life and blood glucose control after starting on flash GM in patients with DM1 under normal clinical practice conditions.

## Material and methods

### Study design

This was an analytical observational study with a prospective cohort design. The study period was from 1 June 2019 to 30 April 2020. The study was approved by the Independent Ethics Committee (PI [Proyecto de investigación {Research Project}] code 19-1390).

### Study objective

The primary objective of this study was to measure changes in the quality of life of patients with DM1 who started on Flash GM. Changes in blood glucose control parameters were also evaluated.

### Participants

The study sample included patients who started treatment with flash GM for the first time and who met the following criteria: 1) having DM1; 2) meeting requirements for the financing of flash GM according to the National Health System; 3) over 18 years old; 4) committed to completing three diabetes education sessions specific to the use of flash GM; and 5) agreeing to take part and sign the informed consent form.

The requirements for the financing of flash GM by the National Health System were: 1) visual disability or severe functional limitations that made it impossible for them to prick their finger, or functional cognitive disorders that caused reduced hypoglycaemia awareness; 2) recurrent hypoglycaemia, understood as episodes at least four times a week or when 10% of the glucose meter readings are below 70 mg/dl after performing an average of six capillary blood glucose tests a day; and 3) actually pregnant or planning to become pregnant.

Patients who met any of the following criteria were excluded: 1) women wishing to become pregnant or pregnant during the study period; 2) language barrier that might compromise learning in the diabetes education sessions; 3) patients with cognitive impairment/mental retardation; and 4) prior use of flash GM.

### Intervention

The following questionnaires were administered, both at baseline and at three months:

1) DTSQ[18] in its Spanish version (EsDTSQ)[19]: eight-question questionnaire, with a score range of 0 (very dissatisfied) to 6 (very satisfied). The maximum total score is 36, equivalent to full satisfaction with the treatment; two of the elements included in the questionnaire, referring to the frequency perceived by the patient of episodes of hyperglycaemia and hypoglycaemia, are analysed individually and descriptively.

2) Specific diabetes quality of life questionnaire (DQOL)[20] in its Spanish version (EsDQOL)[21]: questionnaire that evaluates four spheres overall: a) satisfaction, 15 questions, with a score range of 1 (very satisfied) to 5 (not at all satisfied); b) impact, 17 questions, with a score range of 1 (never) to 5 (always); c) social/vocational concerns, 7 questions, with a score range of 1 (never) to 5 (always); and d) diabetes-related concerns, 4 questions, with a score range of 1 (never) to 5 (always). The minimum score in each of the categories is: 15 points for satisfaction, which implies great satisfaction; 17 points for impact, indicating that diabetes has little impact on day-to-day life; 7 points for social/vocational concerns; and 4 points for diabetes-related concerns, indicating that diabetes causes little worry on a day-to-day basis. The total score is the sum of the scores for each of the sections and ranges from 43 (minimum) to 215 (maximum). In this questionnaire, a lower score indicates a better quality of life.

3) The Diabetes Distress Scale[22] in its Spanish version (EsDDS),[23] which uses 17 questions to assess problem areas that a patient with diabetes may experience in their day-to-day life. Its aim is to evaluate the level of severity of each problem during the past month. These are further grouped into four sub-scales that address a different type of distress: emotional burden, physician distress, regimen distress and interpersonal distress. The score range is from 1 (not a problem) to 6 (very serious problem). The minimum total score is 17 and the maximum is 102. In the EsDDS, a lower score indicates less distress.

4) In addition, the Spanish version of the Clarke questionnaire for hypoglycaemia awareness was administered.[24] It consists of eight questions about patients' awareness of hypoglycaemia, the blood glucose thresholds at which the patient presents symptoms and the number of serious and non-serious episodes. Each response is classified as normal (A) or abnormal (R). The patient's degree of awareness of hypoglycaemia is determined according to the total number of R (1-2R normal awareness; 3R indeterminate awareness; >3R hypoglycaemia unawareness). They were also asked about the total number of hypoglycaemia episodes in the previous two weeks.

All the patients received three diabetes education sessions, two at the beginning and another follow-up session at three months. These were face-to-face or telematic through virtual, individual or group platforms, depending on the case. The device used in all patients was FreeStyle Libre, version 1 (Abbott Diabetes Care, Witney, United Kingdom).

At the first session, before the sensor was applied, the study questionnaires were administered and the following points were explained: fundamentals of flash GM; difference between capillary blood glucose and interstitial glucose concentrations; cases in which capillary blood glucose should be measured; situations in which the information provided by the sensor would be limited; sensor placement and removal; sensor activation, glucose reading and device management; obtaining and interpreting data on their meter; FreeStyle Libre mobile app and remote monitoring by healthcare pro-

fessionals and caregivers; LibreView online platform and download program. Patients then had the sensor applied and activated the monitor, downloaded the FreeStyle Libre mobile app if possible, and switched it on. The patients were linked to the nursing clinic and that of their endocrinologist. Lastly, they were given printed educational information about flash GM and their next appointment was arranged.

At the second session, two weeks later, all the baseline variables were measured. Any doubts expressed by the patients were resolved and the following points were explained: obtaining and interpreting the data for decision making; description and interpretation of the reports in FreeStyle Libre (reader and mobile); description and interpretation of the reports in LibreView; and general recommendations for flash GM.

At the third session, at three months, measurement of the clinical and analytical variables was repeated and the scales were administered again. Once again, any doubts were resolved and the download from the flash GM was assessed, with treatment adjustment recommendations made by the treating endocrinologist, if necessary. No additional educational sessions or educational reinforcement sessions were held.

### Variables

Demographic variables were recorded: age (years), gender. Anthropometric data at baseline and after three months were recorded: weight (kg); height (m); and BMI (kg/m$^2$). At the same points, clinical variables were also assessed: duration of diabetes (years); current treatment (multiple dose insulin [MDI] therapy or treatment with continuous subcutaneous insulin infusion [CSII]). We also assessed the number of daily capillary blood glucose self-tests at baseline before the start of flash GM and at three months.

The following blood glucose control parameters were measured: blood HbA1c (%), assessed by immunoturbidimetry (Cobas c513, Roche Diagnostic, Basel, Switzerland) at baseline, before the start of flash GM and at three months; and the following blood glucose control variables from the Abbott FreeStyle Libre 1 over a 14-day period, at baseline, for the first 15 days, and at three months: percentage of sensor use; mean interstitial glucose concentration (mg/dl); standard deviation (SD); coefficient of variation, defined as the standard deviation between the mean; percentage of time in range (TIR) (70-180 mg/dl); percentage of time in hypoglycaemia (<70 mg/dl); percentage of time in hyperglycaemia (>180 mg/dl) and hypoglycaemic events, defined as the number of episodes with interstitial glucose concentrations <70 mg/dl in 14 days.

### Sample size

The sample size was calculated taking into account an improvement in the DQOL test of at least three points and a sample size of (n = 110) was obtained with a type I error <0.05 and a statistical power of 90%.

### Statistical analysis

The SPSS 23.0 program was used for data analysis(SPSS Inc., Chicago, IL, USA). Quantitative variables were expressed as mean and standard deviation, in brackets, or as median and interquartile range, in square brackets, when the distribution was not normal. Qualitative variables were compared using the Chi-square test, as well as Fisher's exact test when necessary. The distribution of quantitative variables was examined using the Kolmogorov-Smirnov test. For the contrast of hypotheses between quantitative variables, the Student's t test was used, or the Wilcoxon test when the variables did not follow a normal distribution. For all calculations, a probability $p$ less than 0.05 was considered significant. A stratified analysis of the main variables was performed by administration of MDI versus CSII and by HbA1c level greater than 8% (poor blood glucose control) or less than 8% (group with better blood glucose control). This cut-off point was selected in accordance with other similar studies.[3] The ANOVA test was used to adjust the effect of baseline HbA1c and other related variables in the one-sided analysis.

## Results

### Baseline characteristics and use of the device

During the study period, 114 patients met the eligibility criteria. Of these, 56% were male, with a mean age of 37.2 years (12.4). Mean time since onset of diabetes was 18.7 years (11.5). In 28 patients (24.6%), the treatment was CSII, while the rest of the patients were on MDI therapy. At baseline, mean HbA1c was 7.8% (1.3), and was above 8% in 33.3% of patients. None of the patients refused flash GM or dropped out of the study after the baseline visit. The Clarke test was performed before the flash GM, with 17.5% having undetected hypoglycaemia. The number of hypoglycaemic episodes in the two weeks prior to starting flash GM was four [3-7].

Before starting flash GM, the median number of self-tests per day was 6 [4-7], compared to 2 [0-3] at three months ($p$ < 0.001). Of the patients with CSII, the median number of self-tests per day at baseline was 6 [6-8], compared to 1 [0-2] at three months ($p$ < 0.001). Of the users of multiple-dose insulin, the median number of self-tests per day at baseline was 5 [4-6], compared to 2.8 [0-3] at three months ($p$ < 0.001). The median number of scans per day was 11 [8-15] at baseline and 9 [7-11.3] at three months ($p$ < 0.001). The percentage of use of the sensor was 97 [93-98] at 14 days and 96 [91-98] at 3 months.

### Quality of life parameters

#### Treatment satisfaction questionnaire

After starting flash GM, satisfaction with the treatment was found to improve significantly (Table 1).

In the stratified analysis based on baseline HbA1c, there was a significant increase in the EsDTSQ score at three months, both in the group with the worst blood glucose control (HbA1c >8%) (19 [13.8-27] vs 24 [22.5-27]; $p$ < 0.001),

**Table 1** Quality of life questionnaires.

| Questionnaires | Baseline n = 114 | 3 months n = 114 | *p* |
|---|---|---|---|
| EsDTSQ | 22 (15.5-27) | 25 (22-28) | <0.001 |
| EsDQOL | 88 (74-104) | 84 (70-101) | 0.017 |
| Satisfaction | 33 (26.8-39) | 30 (25.8-38) | 0.031 |
| Impact | 34.6 (9.1)[a] | 33.5 (9.6)[a] | 0.155[b] |
| Social/vocational concerns | 11.5 (9-16) | 11 (9-14.3) | 0.262 |
| Diabetes-related concerns | 9 (7-11) | 9 (7-11) | 0.420 |
| EsDDS | 40.5 (26.8-65) | 39.5 (27-58.3) | 0.157 |
| Emotional burden | 14.5 (10-20) | 14 (9-17.3) | 0.005 |
| Physician distress | 5 (4-15.3) | 5 (4-13.3) | 0.423 |
| Regimen distress | 12 (9-21) | 13 (8-18) | 0.444 |
| Interpersonal distress | 5 (3-10) | 5 (3-10) | 0.680 |

In general, the data provide medians and interquartile ranges and the Wilcoxon test was used in all hypothesis testing.
EsDDS: Spanish version of Diabetes Distress Scale; EsDQOL: Spanish version of Specific Diabetes Mellitus Quality of Life Questionnaire; EsDTSQ: Spanish version of Diabetes Treatment Satisfaction Questionnaire.
[a] Mean and standard deviation.
[b] The contrast test was Student's t test.

**Table 2** Quality of life questionnaires based on blood glucose control.

| | HbA1c <8% | | | HbA1c >8% | | |
|---|---|---|---|---|---|---|
| | Baseline | 3 months | *p* | Baseline | 3 months | *p* |
| EsDTSQ | 21.8 (6.8)[a] | 25.6 (5)[a] | <0.001[b] | 19 (13.8-27) | 24 (22.5-27) | <0.001 |
| EsDQOL | 86.9 (18.8)[a] | 82.7 (19.9)[a] | 0.019[b] | 94.3 (22.5)[a] | 93.5 (25.5)[a] | 0.728[b] |
| EsDDS | 37 (26-62) | 35 (25.3-46.8) | 0.010 | 51.4 (20.5)[a] | 53.8 (23.6)[a] | 0.351[b] |

In general, the data provide medians and interquartile ranges and the Wilcoxon test was used in all hypothesis testing.
EsDDS: Spanish version of Diabetes Distress Scale; EsDQOL: Spanish version of Specific Diabetes Mellitus Quality of Life Questionnaire; EsDTSQ: Spanish version of Diabetes Treatment Satisfaction Questionnaire.
[a] Mean and standard deviation.
[b] The contrast test was Student's t test.

and in the group with better blood glucose control (21.8 (6.8) vs 25.6 (5); $p < 0.001$) (Table 2).

In the stratified analysis according to the form of insulin administration (MDI vs CSII), a significant increase was found in the EsDTSQ score at three months in the multiple-dose insulin group (19.7 (7) vs 24.4 (4.7); $p < 0.001$) and in the CSII group (26 [20-29] vs 27.5 [24-31]; $p = 0.04$) (Table 3).

### Specific quality of life questionnaire for diabetes mellitus

A significant improvement in quality of life was found after starting flash GM (Table 1).

In the stratified analysis based on baseline HbA1c, in the group with poor blood glucose control (HbA1c >8%), no statistically significant differences were found in the EsDQOL score at three months (94.3 (22.5) vs 93.5 (25.5); $p = 0.728$). In the group of patients with better blood glucose control, a significant decrease was found in the EsDQOL score at three months (86.9 (18.8) vs 82.7 (19.9); $p = 0.019$) (Table 2).

In the stratified analysis according to the form of insulin administration (MDI vs CSII), a significant decrease was found in the EsDQOL score in the MDI group at three months (91.67 (19.9) vs 87.8 (22.6); $p = 0.009$). In contrast, no statistically significant differences were found in the CSII group (75.5 [67-94] vs 77.5 [66-91]; $p = 0.829$) (Table 3).

### Diabetes Distress Scale

With regard to the distress associated with diabetes, the differences in the EsDDS score after starting flash GM were not statistically significant (Table 1).

In the stratified analysis based on baseline HbA1c, in the group with poor blood glucose control (HbA1c >8%) there was no decrease in the EsDDS score at three months (51.4 (20.5) vs 53.8 (23.6); $p = 0.351$). In the group of patients with better blood glucose control, there was a significant decrease in the EsDDS score at three months (37 [26-62] vs 35 [25.3-46.8]; $p = 0.010$) (Table 2).

In the stratified analysis according to the form of insulin administration (MDI vs CSII), no statistically significant differences were found in the EsDDS score at three months in the MDI group (43 [28-67] vs 41 [29-65]; $p = 0.770$). In contrast, in the CSII group, there was a significant increase in the EsDDS score at three months (31.5 [24-63] vs 32 [22-45]; $p = 0.008$) (Table 3).

## Blood glucose control parameters

### Blood HbA1c

A significant reduction in HbA1c was found at three months (7.8 (1.3) vs 7.4 (1.1); $p < 0.001$) (Table 4).

**Table 3** Quality of life questionnaires according to treatment modality.

| | MDI | | | CSII | | |
|---|---|---|---|---|---|---|
| | Baseline | 3 months | *p* | Baseline | 3 months | *p* |
| EsDTSQ | 19.7 (7)[a] | 24.4 (4.7)[a] | <0.001[b] | 26 (20-29) | 27.5 (24-31) | 0.04 |
| EsDQOL | 91.67 (19.9)[a] | 87.8 (22.6)[a] | 0.009[b] | 75.5 (67-94) | 77.5 (66-91) | 0.829 |
| EsDDS | 43 (28-67) | 41 (29-65) | 0.770 | 31.5 (24-63) | 32 (22-45) | 0.008 |

In general, the data provide medians and interquartile ranges and the Wilcoxon test was used in all hypothesis testing.
CSII: continuous subcutaneous insulin infusion; EsDDS: Spanish version of Diabetes Distress Scale; EsDQOL: Spanish version of Specific Diabetes Mellitus Quality of Life Questionnaire; EsDTSQ: Spanish version of Diabetes Treatment Satisfaction Questionnaire; MDI: multiple dose insulin.
[a] Mean and standard deviation.
[b] The contrast test was Student's t test.

**Table 4** Flash GM blood glucose control variables and plasma HbA1c.

| Blood glucose control variables | Initial n = 114 | 3 months n = 114 | *p* |
|---|---|---|---|
| Plasma HbA1c (%) (baseline) | 7.8 (1.3)[a] | 7.4 (1.1)[a] | <0.001[b] |
| Mean blood glucose (mg/dl) | 162.5 (142-185) | 166.5 (147-188.5) | 0.035 |
| Standard deviation | 67 (57-78) | 67 (55.8-78) | 0.645 |
| Coefficient of variation | 41 (37-46) | 40 (36-44.3) | 0.049 |
| % time in hypoglycaemia (<70 mg/dl) | 6 (3-11) | 5 (3-9.3) | 0.213 |
| % time in hyperglycaemia (>180 mg/dl) | 37.1 (16.3)[a] | 39.8 (16.9)[a] | 0.016[b] |
| % TIR (70-180 mg/dl) | 55.4 (14.5)[a] | 53.3 (16.1)[a] | 0.036[b] |
| No. of hypoglycaemia events % (<70 mg/dl in 14 days) | 14 (9)[a] | 11.5 (7)[a] | <0.001[b] |

HbA1c: glycosylated haemoglobin; TIR: time in range.
In general, the data provide medians and interquartile ranges and the Wilcoxon test was used in all hypothesis testing.
[a] Mean and standard deviation.
[b] The contrast test was Student's t test.

In the stratified analysis based on baseline HbA1c, there was a significant decrease in the HbA1c value at three months in the group with poor blood glucose control (HbA1c >8%) (8.6% [8.4-9.6] vs 8% [7.7-8.6]; $p < 0.001$), but not in the group with better blood glucose control (7.1% [6.6-7.5] vs 7% [6.6-7.5]; $p = 0.5$).

In the stratified analysis according to the form of insulin administration (MDI vs CSII), there was a significant decrease in the HbA1c value at three months in the MDI group (7.8% [7-8.5] vs 7.5% [7-8]; $p < 0.001$), but not in the CSII group (7.3% (0.9) vs 7.1% (0.5); $p = 0.133$).

### Flash GM blood glucose control variables from flash glucose monitoring

Table 4 shows the changes in the blood glucose control variables obtained from downloading 14 days of the flash GM data, at the start of flash GM and at three months.

## Discussion

In our cohort of adult patients with DM1, starting flash GM was associated with an improvement in quality of life and in the satisfaction scale. Benefits were also found in blood glucose control, by optimising the plasma HbA1c level and reducing episodes of hypoglycaemia in 14 days.

The previous studies carried did not report changes in quality of life associated with the starting flash GM.[12,15] This could be related to patient education on the proper use of flash GM. Patients did not receive prior training in flash GM in all the published studies,[12] and any training given was often limited to one single session.[15] The improvement in quality of life found in our study could be related to closer follow-up and more time dedicated to diabetes education for flash GM.[15,17] It was striking in our study that patients with CSII had a healthier profile, greater satisfaction with treatment and better quality of life but more diabetes-related distress. Future studies should therefore consider the treatment modality as a covariate of interest.

In our study, flash GM was extremely well accepted by patients. The decrease in the number of daily self-tests and the high rate of data captured at three months were findings suggestive of that, and were similar to those from a sub-analysis of the IMPACT study.[25] Flash GM can be very useful in decision-making in diabetes self-care.[26] The improvement in quality of life in the group of patients on MDI may be related to the perceived reliability of and confidence in the system felt by the patients. In contrast, in the CSII group we could not rule out that the differences we found may have been down to chance. There are reports of improvement in quality of life associated with the use of integrated continuous monitoring systems with insulin pump.[27] Improved quality

of life was found in patients with better baseline blood glucose control, and this could possibly be related to a greater awareness of their disease.

In terms of treatment satisfaction when using flash GM, measured with the EsDTSQ, the feedback from our patients was positive. These data are in line with those reported by randomised clinical trials[12] and observational studies.[3,13–15] As has been described in the literature, the combination of flash GM and a structured diabetes education programme for flash GM may have contributed to these positive results.[15] Furthermore, diabetes self-care could also be an important factor. In our study, satisfaction with treatment was reported by both patients with poorer baseline blood glucose control and those with better blood glucose control. We also found acceptance of flash GM in both forms of insulin administration studied.

We were unable to demonstrate changes in diabetes-related distress, as assessed by the EsDDS scale, after starting flash GM. Some studies that evaluated distress using the same scale did report reductions in the mean score.[2,5,28] However, other studies examining diabetes-related depression or anxiety using different scales have shown inconsistent results.[3,13] We found in our sample that diabetes-related distress improved in patients with a prior better degree of blood glucose control, perhaps due to the greater availability of information and feeling of being in control. The increase in distress in patients with CSII could be related to them having a second device that is not interconnected, in which case, it could be minimised by the use of hybrid closed-loop systems.

With regard to the effect of starting flash GM on blood glucose control, we found an improvement in HbA1c three months after starting treatment, which is in line with findings from observational studies[3,5,7–9,29,30] and studies in actual clinical practice.[2,4,10,16] This effect was particularly pronounced in subjects with poorer baseline blood glucose control, who may have greater room for improvement, similar to findings in other studies.[3] Analysing the change in HbA1c depending on the treatment modality, we found a statistically significant decrease in patients with MDI, which had not been reported in other studies.[25] However, although we did identify a trend towards significance, we were unable to demonstrate a similar decrease in the CSII group, which had been reported in other studies.[7]

After starting flash GM, there was a decrease in the number of hypoglycaemic events, although without a reduction in the time in hypoglycaemia, the value for which reached statistical significance. However, the lack of improvement in other blood glucose parameters could be related to a lack of statistical power, a short follow-up period or a decrease in the number of daily scans at three months.[16] The TIR decreased as a result of the increase in the percentage of time in hyperglycaemia. This contrasted with the decrease in plasma HbA1c, as a reduction in TIR and increased time in hyperglycaemia would work against an improvement in the patient's blood glucose control. However, HbA1c might not be a sufficiently precise parameter and the use of a measure that would analyse the clinical status of the patient in the actual period of time when the data were analysed, such as the Glucose Management Indicator, would perhaps be more appropriate.

Our study is not without its limitations. It was a single-centre study, meaning it may not be representative of other places in view of the demographic characteristics and the health and social care system. Also, the follow-up was evaluated after a short period of time. Future studies should determine whether the improvement in quality of life is maintained over time or is related to the novelty of starting flash GM. There were results observed in subgroups of patients that perhaps need to be specifically examined in future studies. Some parameters were initially measured after the patients had already started receiving data from the sensor and were therefore already benefiting from the monitoring. Future studies should consider placing a blind sensor at baseline and also evaluating patients with poor blood glucose control and poor treatment adherence. Among the study's strengths are that it was a prospective study, which included patients right from the beginning of public financing of the flash GM system, and that it involved specific training of patients in a minimum of three sessions, which is a key element for the proper use and interpretation of flash GM.

## Conclusions

Starting flash GM, associated with a structured educational programme, in adult patients with DM1 was associated with an improvement in quality of life and greater satisfaction with diabetes treatment. We were unable to demonstrate that diabetes-related distress measured through the EsDDS scale improved after the use of flash GM. HbA1c and the number of hypoglycaemic events improved, but not the rest of the blood glucose parameters.

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## Conflicts of interest

None.

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