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Clinical Research Article

Impact of COVID-19 Lockdown on Glycemic Control in Adults with Type 1 Diabetes Mellitus

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Abbreviations: CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; FGM, flash glucose monitoring; GMI, glucose management indicator; HbA1c, glycosylated hemoglobin; TIR, time in range; T1DM, type 1 diabetes mellitus.

Abstract

Aim. To examine the impact of the lockdown caused by the COVID-19 pandemic on both the glycemic control and the daily habits of a group of patients with type 1 diabetes mellitus (T1DM) using flash continuous glucose monitoring devices (flash CGMs).

Methods. Retrospective analysis based on all the information gathered in virtual consultations from a cohort of 50 adult patients with T1DM with follow-up at our site. We compared their CGM metrics during lockdown with their own previous data before the pandemic occurred, as well as the potential psychological and therapeutic changes.

Results. We observed a reduction of average glucose values: 160.26 ± 22.55 mg/dL vs 150 ± 20.96 mg/dL, $P = .0009$; estimated glycosylated hemoglobin: $7.21 \pm 0.78\%$ vs $6.83 \pm 0.71\%$, $P = .0005$; glucose management indicator $7.15 \pm 0.57\%$ vs $6.88 \pm 0.49\%$; $P = .0003$, and glycemic variability: 40.74 ± 6.66 vs 36.43 ± 6.09 $P < .0001$. Time in range showed an improvement: $57.46 \pm 11.85\%$ vs a $65.76 \pm 12.09\%$, $P < .0001$, without an increase in percentage of time in hypoglycemia.

Conclusions: COVID-19 lockdown was associated with an improvement in glycemic control in patients with T1DM using CGMs.

Key Words: COVID-19, type 1 diabetes mellitus, continuous glucose monitoring (GCM), lockdown, ambulatory glucose profile

The COVID-19 pandemic is the biggest global health emergency we have known in the last 100 years. Its great impact on our lives involves totally breaking with many social harmony rules, which will remain affected by this pandemic to an extent, at least in the near future. Spain, and especially Madrid, has been one of the worst affected places. Governments from different countries have been forced to adopt legal measures in the critical infection phase to slow down the spread of the COVID-19. On March 14, 2020, the Spanish government released an executive order

for exceptional circumstances for the management of the health crisis caused by COVID-19.

Our study covers a period of 14 days from 11 April onwards, for we consider that it was the most difficult phase of lockdown after spending 4 weeks in a state of alarm, a situation that involved strict measures such as complete confinement at home, social distancing unless unavoidable, and the shutdown of all businesses except those with essential workers. Lockdown has involved a drastic change in everyone's daily habits as well as in family, social, and work relationships with evident psychosocial consequences [1, 2].

According to the health authorities, people with diabetes seem to be one of the groups most vulnerable to COVID-19. Therefore, scientific organizations have established specific recommendations to avoid contagion of the virus and to assist management of the disease [3]. The restrictive measures mentioned above, the perception of being in a high-risk group for COVID-19, and the determinants inherent to the disease itself entail an important emotional impact on people with diabetes [4]. Moreover, people with type 1 diabetes mellitus (T1DM) might require therapeutic adjustments, quite complex sometimes, to maintain the objectives of metabolic control.

This research aims to study the impact of social and work confinement on glycemic control in a cohort of patients with T1DM who use continuous glucose monitoring devices (CGMs). To that end, we analyzed the ambulatory glucose profiles of patients as well as detailed all the modifications in their daily habits, and, simultaneously, compared them with the patient's data previous to the announcement of the state of alarm.

Materials and Methods

This retrospective study was conducted based on CGM metrics of patients with T1DM using flash glucose monitoring (FGM) (FreeStyle Libre®, Abbott), most of them in a multiple dose of insulin injection therapy with a basal bolus regimen, carried out in the virtual consultations.

Data download from the devices was made using the Libreview platform, all corresponding to a 14-day period before and during lockdown, and both ambulatory glucose profiles for each device were compared. No intermediate visits were conducted. All the recommendations gathered in the International Consensus of CGM were followed [5], analyzing the following variables: percentage of device usage, average daily readings, average glucose, estimated glycosylated hemoglobin (HbA1c), glucose management indicator (GMI), coefficient of variation, time in range (TIR), percentage

of time below range (<70 mg/dL), number of low glucose events, and total time (minutes) of registers below 70 mg/dL. Virtual consultations were conducted following an established script with standardized questions to ensure that we collected the same data from all the subjects. These interviews collected information regarding follow-up during lockdown, emotional pattern, estimated variations of body weight, adjustments in the insulin doses, home daily physical activity, work situation, symptoms compatible with COVID-19 infection, and specific diagnostic tests for the coronavirus. The standardized questions are available elsewhere (all supplementary material and figures are located in a digital research materials repository [6]).

Statistical Analysis

Descriptive results were expressed as mean ± standard deviation (SD) or median and 25th percentile/75th percentile, as appropriate, while qualitative variables are presented as relative percentages of samples (histograms) included in contingency tables. To analyze the impact on glycemic control, the difference of mean glucose between visit 1 and visit 2 was calculated for each patient. We used the paired Student t-test to analyze 2 related samples. One-way analysis of variance was performed to compare more than 2 groups, and post hoc multiple comparisons were made with Tukey's test. A nonparametric variant was used to analyze differences between groups when normality was not achieved in the reported variable (Mann–Whitney U or Kruskal–Wallis analysis of variance, as appropriate). Similarly, comparison between related samples was performed using the Wilcoxon sum rank test when normality was not achieved. Additionally, Pearson's correlation analyses were performed to detect difference of mean glucose between visit 1 and visit 2 and clinical parameters. Stata v. 12.0 for Windows and R version 3.3.2 were used for analyses. Stata and Package corrplot (available from: https://github.com/taiyun/corrplot) were used for graphics. The P-values were 2-sided and statistical significance was considered when $P < .05$; data are presented for $P < .05$, $P < .01$ and $P < .001$.

Ethics Approval and Consent to Participate

Ethics approval was granted by the local Research Ethics Committee of the University Hospital la Princesa in accordance with the Declaration of Helsinki. All the participants agreed to give oral consent prior to their inclusion in the study.

Results

Patients Characteristics

A cohort of 50 patients with T1DM that uses FGM devices was analyzed. The mean age was 43 (18-86) years old, mean duration of T1DM was 22.24 ± 12.21 years, body mass index was 24.14 ± 2.7 kg/m^2 and the average HbA1c was 7.3% (5.6-9.3) at the last visit prior to lockdown. The frequency of medical consultations for these patients at our site was every 3 to 4 months. The median time of use for the CGM before lockdown was 21 months (range 5-51). Forty-five patients followed a basal bolus regimen whereas 5 of them used a continuous subcutaneous insulin infusion system. Total daily dose of insulin was 39.26 ± 17.91 IU. Table 1 shows descriptive data of the analyzed sample.

Virtual Consultations Data

Virtual consultations were carried out for every patient included in the study. From the total number of participants in the study, just 1 presented with COVID-19 infection, confirmed by the polymerase chain reaction test. A second 1 was diagnosed by serological tests with positive immunoglobulin G, without a previous polymerase chain reaction test. Apart from those 2 confirmed cases, 3 other patients consulted their general practitioner with symptoms compatible with COVID-19 infection. They were advised to self-isolate at home even though no diagnostic test was carried out to confirm the disease. The 5 patients aforementioned described all symptoms as mild, and none of them needed hospital admission.

Data regarding follow-up during lockdown, emotional pattern, estimated variations of body weight, insulin dose adjustments, home daily physical activity, work situation

Table 1. Basal characteristics of the patient sample included in the study

	Total number of participants n = 50
Female gender, n (%)	27 (54)
Age, years	43.4 ± 15.6
Diabetes duration, years	22.24 ± 12.21
Insulin regime, n (%)	
MDI	45 (90)
CSII	5 (10)
Total daily dose of insulin– IU	39.26 ± 17.91
HbA1c, %	7.3 ± 0.8
BMI, kg/m^2	24.14 ± 2.7

± values are the mean ± standard deviation.
Abbreviations: MDI, multiple doses of insulin injection; CSII, continuous subcutaneous insulin injection system; IU, international units; BMI, body mass index.

in addition to the compatible symptoms for COVID-19 infection, and all the specific COVID-19 diagnostic tests performed are summarized elsewhere [6].

Regarding the working situation, most of the interviewed patients were working from home (n = 17), 7 were unemployed, 3 were on temporary layoff, 3 were in nonhealth-related essential work, and 3 reported to be on sick leave because of T1DM and 2 more for other nonspecified reasons. Just 1 patient was on sick leave for COVID-19 infection. Two of the patients presented a disability, the rest being either retired (n = 9) or students (n = 3)

As for their personal situation during the lockdown, the vast majority of the interviewed people (44%) claimed that they did not go out, not even for permitted activities (such as grocery shopping, pharmacy visits, walking their pets), 22% of them did it very occasionally (this was considered as a maximum of once every 2 weeks), and 16% just a maximum of twice a week. The remaining 18% confirmed that they went out more than twice a week. Almost all of the patients claimed that they had adapted to the lockdown situation but nevertheless were able to carry out some form of exercise (76%), as opposed to 24% that did not practice any kind of activity. Regarding body weight, most of the interviewed subjects did not note any noticeable changes in body weight (62%), whereas 28% presented weight gain, 2 kg being the most frequent weight gain mentioned (18%). Some patients disclosed losing weight (10%), varying from 1 kg to 3 kg.

As for the emotional pattern, nearly half of the patients (48%) stated that they had not noted any evident changes in their mood in relation to their diabetes or the potential impact because of the lockdown. The other half mentioned different emotions such as fear (28%), anxiety (22%), sadness (16%), and stress (16%).

In relation to the impact of lockdown in insulin dose adjustment, 38% needed an increase in their total daily dose of insulin, against 36% that maintained their usual treatment without any changes. The most frequent insulin dose increase in those patients who needed an upward adjustment in their treatment was 2 IU (12%), followed by 3 to 5 IU in 8% of the subjects. For those who had to decrease their total daily insulin dose (26%), this was usually no more than 2 IU (10%)

Ambulatory Glucose Profile

An improvement was observed in average glucose (Fig. 1A) from 160.26 ± 22.55 mg/dL prior to lockdown to 150 ± 20.96 mg/dL during that time, P = .0009. Likewise, both estimated HbA1c (Fig. 1B) and GMI (Fig. 1C) decreased, 0.37% (7.21 ± 0.78% [before] vs 6.83 ± 0.71% [during], P = .0005) and 0.28% (7.16 ± 0.57% [before] vs 6.88 ±

0.49% [during], *P* = .0003), respectively. We further observed an improvement of the time in range (defined as target range of 70-180 mg/dL) from 57.46 ± 11.85% (before lockdown) to 65.76 ± 12.09% (during lockdown), *P* < .0001 (Fig. 1D), as well as a decrease in glycemic variability (from 40.74 ± 6.66 before lockdown to 36.43 ± 6.09 during this period, *P* < .0001) (Fig. 1E).

The number of hypoglycemic events, defined as blood glucose levels <70 mg/dL during at least 15 minutes, (Fig. 1F) improved from a median of 13 (7-19) before the

lockdown to 9 events (6-17) during lockdown, as well as the percentage of time below range (7.48 ± 5.23% to 6.28 ± 5.26%), but these differences were not significant, as they were not for the total time of hypoglycemia either (100.5 minutes (79-118) before lockdown vs 101 minutes (79-133) (during lockdown). In contrast, no significant differences were noted in variables related to adherence to the CGM device or regarding the number of readings done before and during lockdown (10 readings [8-13] [before] vs 10 readings [8-14] [during], nor in the percentage
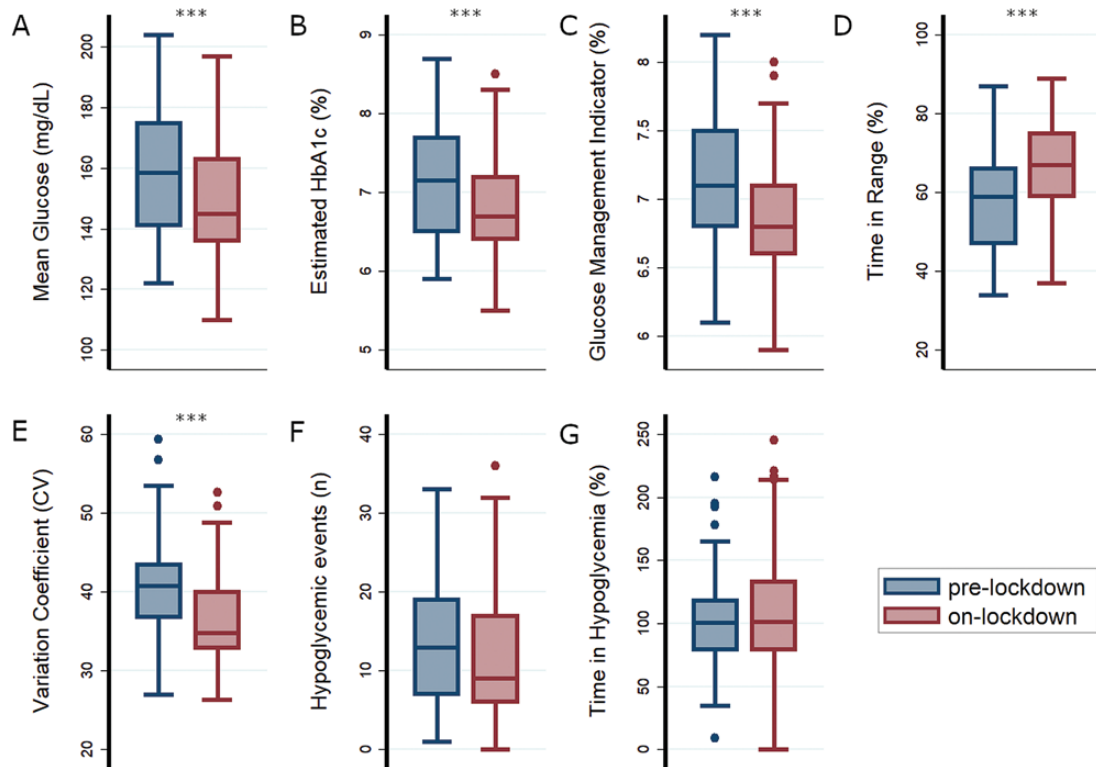

Figure 1. Glucose ambulatory profile improvement during lockdown. Box plots of CGM metrics from Ambulatory Glucose Profile forms before and during lockdown (*P < .001, **P < 0.01, ***P < .001). The dots are outliers, which are defined as those values that are outside the range. This is calculated by multiplying 1.5 by the interquartile range.

Table 2. Comparison of the CGM metrics from the Ambulatory Glucose Profile forms before and during lockdown

	Before n = 50	During n = 50	Difference P
Readings, number (range)	10 (8–13)	10 (8–14)	.62
Time CGM is active, %	96.52 ± 5.11	97.46 ± 4.35	.4
Mean glucose, mg/dL	160.26 ± 22.55	150 ± 20.96	.0009
Estimated hbA1c, %	7.21 ± 0.78	6.83 ± 0.71	.0005
GMI, %	7.16 ± 0.57	6.88 ± 0.49	.0003
CV, %	40.74 ± 6.66	36.43 ± 6.09	<.0001
Time in range, %	57.46 ± 11.85	65.76 ± 12.09	<.0001
Time below range (<70 mg/dL), %	7.48 ± 5.23	6.28 ± 5.26	.14
Hypoglycemic events, number (range)	13 (7–19)	9 (6–17)	.62
Total time <70 mg/dL (minutes), number (range)	100.5 (79–118)	101 (79–133)	.75

Abbreviations: CGM, continuous glucose monitoring; GMI, glucose management indicator; CV, coefficient of variation.

of time that the CGM was active (96.52 ± 5.11% [before] vs 97.46 ± 4.34% [during]). Table 2 shows a comparison of the CGM metrics that has been previously detailed, following the recommendations from the International Consensus about CGM. When patients are analyzed individually, certain subjects had worse glycemic outcomes during lockdown. However, these are small differences and much less remarkable than those who improved compared with their previous data.

Exploratory Analysis of Clinical Predictors of the Impact on Glycemic Control of the COVID-19 Pandemic

We analyzed the influence of clinical predictors on glycemic control during the COVID-19 pandemic. There is a tendency towards a slightly positive correlation between older patients (>50 years old) and a worsening in glycemic control during lockdown compared with the youngest ones ($P = .08$) (Fig. 2A).

However, there was no significant correlation between gender and impact of lockdown on glycemic control (Fig. 2B). No other significant differences were noted during lockdown regarding mean duration of TIDM and gender. Nonetheless, positive significant correlations were

found before and during lockdown between the glucose mean difference and both the body mass index and total daily insulin dose (Fig. 2C).

Lastly, when we analyzed the correlations between the working situation and glycemic control, we found higher frequency of better glycemic control (categorized as those that had a lower mean glucose con visit 2 compared with visit 1) on sick leave, those with essential work, those working from home, those unemployed or o a layoff situation, and for retired subjects (a balloon plot is shown elsewhere [6]).

Discussion

The new infection of COVID 19 has caused a great health emergency crisis and was declared as a global pandemic by the World Health Organization on March 11, 2020. The clinical evidence gathered from different countries indicate that diabetes has a high prevalence among patients with COVID-19. The percentage of infected people with diabetes according to different studies may vary [7, 8]. Nonetheless, there is unanimity to consider diabetes as a high prevalence condition in severe cases of COVID 19 infection and it is associated with an overall higher morbidity and mortality rate [8, 9]. All of this has been decisive for
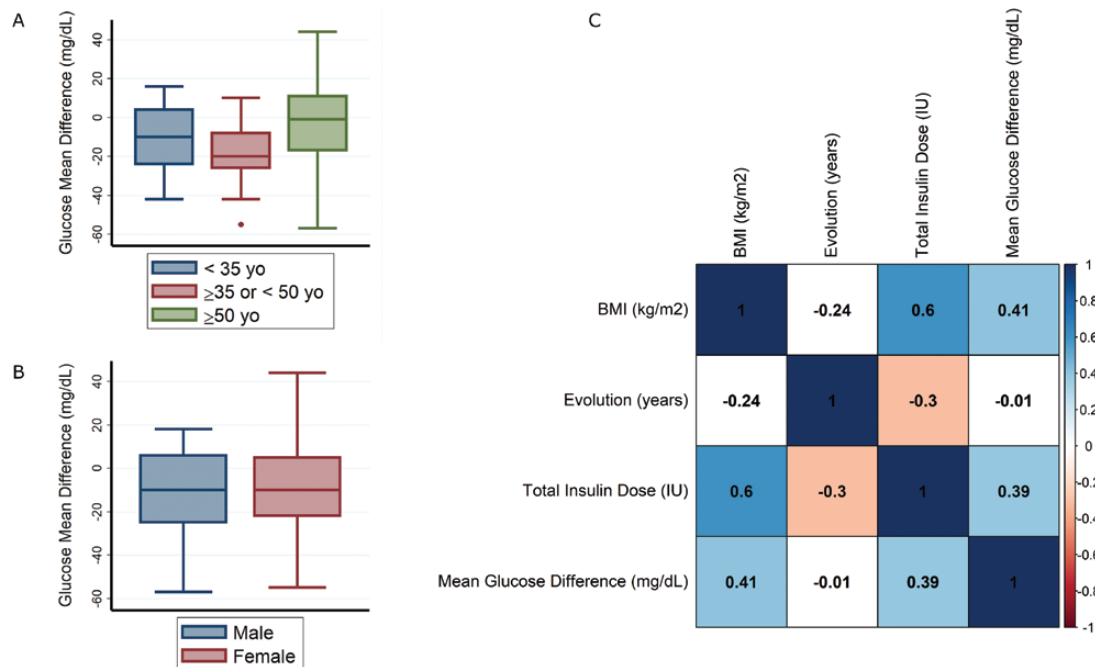

Figure 2. Exploratory [analysis of clinical predictors of COVID-19 impact in glycemic control. (A) Box plots of mean glucose difference values before and during lockdown in 3 different groups of age (<35, ≥35–50, and ≥50 years old). (B) Box plots of mean glucose difference values before and during lockdown regarding gender. (C) Correlation map of clinical predictors of glycemic control. Values represent the Pearson's correlation coefficient (r). Significant negative correlations are shown in orange and significant positive correlations in blue. Color intensity increases with the magnitude of correlation. The white ones indicate a coefficient with non-significant correlation.

the health authorities to include people with diabetes as a vulnerable group for COVID-19.

The susceptibility of the population with diabetes to COVID-19 infection is based on a greater predisposition to infections as a consequence of leukocyte dysfunction, the proinflammatory profile, and the microangiopathic changes which affect the lungs [10-12]. However, further investigations are needed to clarify important concerns such as what is the real risk of contagion in people with diabetes [9, 13, 14], its influence in the evolution of the disease, and how the impact is determined according to ethnicity, age, gender, and type of diabetes, as well as other comorbidities and associated complications [15, 16].

The infection rate observed in our study matches the expected one for the general Spanish population [17], even though our patients' diagnostic tests were merely anecdotal. It is important to highlight that when we conducted our study the recommendation from the health authorities when having mild symptoms compatible with COVID-19 was to self-isolate at home and to avoid going to the hospitals unless persistence and/or worsening of the symptoms. On the other hand, we have to emphasize that neither the patients that had a confirmed diagnosis through the test nor the ones that just consulted their GP with compatible symptoms presented a severe clinical picture and none of them required hospitalization.

Currently, the only effective and efficient tool to avoid infection with the disease is prophylaxis derived from hygiene and protective measures. Home confinement has been one of the measures that governments from countries all around the world have been forced to establish, especially in those more affected by the virus. For the general population, this has involved a drastic change in their lifestyle, as well as in their family, social, and work relationships, which will undoubtedly lead to psychosocial consequences [1, 2].

In recent years, the literature has described the effect of diverse natural disasters on glycemic control in patients with diabetes [18-22]. However, the current pandemic is very different from other scenarios that have been previously described [23].

CGM devices are perhaps one of the main technological innovations in the field for T1DM and whose gradual implementation, supported by public funding in many countries, has become a very important tool for self-care in people with T1DM. CGM provides continuous feedback through a better knowledge of the glycemic pattern and, consequently, it can facilitate therapeutic adjustments, which translates into improved metabolic control [24]. During the past months it was advised to avoid going to hospitals unless strictly necessary, which has highlighted the importance of online platforms for glucose management. The possibility of sharing virtually all glycemic data through downloaded software has actually become an essential part of online consultations between patients and health professionals [25].

Lockdown for a person with T1DM may entail a very complex situation in regard to glycemic control, such as rearrangements in different realms including times, diet, physical activity, family and/or work stress, daily routines, and so on, which, altogether, may actually provoke changes in glycemic control [26, 27]. However, there are barely described significant differences regarding the effects of lockdown on glycemic control in people with T1DM [28]. In our cohort of patients the CGM metrics, shown in the ambulatory glucose profile through the data download, improved substantially during the lockdown compared with the previous period. Although we do not know whether the 14-day prelockdown period of CGM data is representative of typical life (this period could have included a period of illness or change in exercise that is not accounted for) the estimated HbA1c values obtained in the data download before lockdown (7.21 ± 0.78%) did not show differences compared with the mean HbA1c values of the last 3 months obtained from their medical records (HbA1c 7.3 ± 0.73%), $P = .2517$. Therefore, we believe that the analyzed data are representative. We observed significant differences in mean glucose, estimated HbA1c, GMI, glycemic variability, and time in range compared with the period of time before the state of alarm, all of this without an increase in the percentage of time in hypoglycemia. With regard to glycemic variability, the result obtained in the analysis showed a reduction in the coefficient of variation, which means that half of the patients would reach the goal of low glycemic variability (<36%).

We consider that the stability of the household routine and the absence of the usual daily stress levels could have surpassed the negative aspects derived from the situation of the state of alarm. In the analyzed patients, it does not seem that gender or the time of evolution of the disease were determinant in all the changes in glycemic control. There could be a tendency towards a worsening in glycemic control during lockdown in the older patients. However, this was a small difference; a bigger cohort of subjects would be needed in order to detect the actual difference.

Although, to date, we cannot explain the underlying reasons for our results, we hypothesized, due to minimum insulin adjustments and relative stability of body weight in a vast majority of the analyzed patients, that they have been able to balance food intake, home exercise, and insulin requirements to counteract the consequences of physical inactivity as well as the psychosocial impact. This demonstrates their high level of awareness, which may have contributed to the clear improvement in the CGM metrics.

As other authors suggest [4, 29, 30] people with diabetes have developed specific concerns regarding COVID-19 related to diabetes. Many patients show their apprehension at belonging to a specific high-risk group and the potential added complications that they could present should they become infected. We believe that this self-perception of vulnerability is consistent with the high degree of compliance with home isolation carried out by most of our patients.

This study has potential limitations. We would point out the small sample size since it decreases the statistical power, lack of accuracy and detail of the interview to explain the psychosocial impact of home confinement properly, and the subjective bias of the answers from the interviewed patients, and we used nonvalidated questionnaires. Therefore, we are aware that firm conclusions are very difficult to ascertain. Moreover, even if we usually ask patients in their routine consultations about their physical activity and exercise habits, we have not made a comparison of these data prior to and during lockdown, so it could be another limitation of our study. It is difficult to assess the exact reason for the improvement, and 1 of the reasons could have been focusing more attention on their diabetes. Despite that, our study clearly reflects the daily habits as well as glycemic control through the data download with FGM in a cohort of patients with T1DM during the period of lockdown caused by the COVID-19 health crisis. It was concluded that there was an improvement in the majority of analyzed CGM metrics compared with the beginning of the pandemic.

As a final thought, we truly believe that the experience gained during the COVID-19 crisis implies a turning point in the near future [5] and it will also help to consolidate the implementation of a virtual consultation model that could coexist with the traditional on-site one, which will also change the relationship pattern between patients with diabetes and health professionals.

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Additional Information

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