Randomized Study to Evaluate the Impact of Telemedicine Care in Patients With Type 1 Diabetes With Multiple Doses of Insulin and Suboptimal HbA_{1c} in Andalusia (Spain): PLATEDIAN Study

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OBJECTIVE

To assess the impact of a telemedicine visit using the platform Diabetic compared with a face-to-face visit on clinical outcomes, patients' health-related quality of life (HRQoL), and physicians' satisfaction in patients with type 1 diabetes.

RESEARCH DESIGN AND METHODS

PLATEDIAN (Telemedicine on Metabolic Control in Type 1 Diabetes Mellitus Andalusian Patients) (NCT03332472) was a multicenter, randomized, 6-month follow-up, open-label, parallel-group controlled study performed in patients with type 1 diabetes with suboptimal metabolic control (HbA_{1c} <8% [<64 mmol/mol]), treated with multiple daily injections. A total of 388 patients were assessed for eligibility; 379 of them were randomized 1:1 to three face-to-face visits (control cohort [CC]) ($n = 167$) or the replacement of an intermediate face-to-face visit by a telemedicine visit using Diabetic (intervention cohort [IC]) ($n = 163$). The primary efficacy end point was the mean change of HbA_{1c} levels from baseline to month 6. Other efficacy and safety end points were mean blood glucose, glucose variability, episodes of hypoglycemia and hyperglycemia, patient-reported outcomes, and physicians' satisfaction.

RESULTS

At month 6, the mean change in HbA_{1c} levels was −0.04 ± 0.5% (−0.5 ± 5.8 mmol/mol) in the CC and 0.01 ± 0.6% (0.1 ± 6.0 mmol/mol) in the IC ($P = 0.4941$). The number of patients who achieved HbA_{1c} <7% (<53 mmol/mol) was 73 and 78 in the CC and IC, respectively. Significant differences were not found regarding safety end points at 6 months. Changes in HRQoL between the first visit and final visit did not differ between cohorts, and, regarding fear of hypoglycemia (FH-15 score ≥28), statistically significant differences observed at baseline remained unchanged at 6 months ($P < 0.05$).

CONCLUSIONS

The use of telemedicine in patients with type 1 diabetes with HbA_{1c} <8% (<64 mmol/mol) provides similar efficacy and safety outcomes as face-to-face visits.

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**A complete list of the Diabetes Group of SAEDYN (Andalusian Society of Endocrinology, Diabetes, and Nutrition) can be found in the Supplementary Data.*

Diabetes is a complex chronic disease that requires continuous medical care with multifactorial risk reduction strategies beyond glycemic control (1). It is associated with high comorbidity, disability, and premature death (1,2). In Spain, the management of diabetes entails a significant burden on the health care system, mainly associated with the use of resources (2).

Type 1 diabetes management poses a challenge for health care providers (3). Strict glycemic control prevents acute complications and reduces the risk of cardiovascular disease and microvascular complications (4,5). Metabolic control is achieved by monitoring glucose levels, following dietary recommendations, and evaluating the correct dose of insulin for administering (6). Poor metabolic control is associated with short-term complications such as hypoglycemia, poor adherence to treatment regimens, and noncompliance with scheduled visits to the doctor (3,7).

Telemedicine is defined as the delivery of health care services using information and communication technologies with the aim of diagnosing, treating, and preventing diseases and injuries (8). Telemedicine has been shown to be a valuable tool to manage chronic conditions such as hypertension (9) or chronic obstructive pulmonary disease (10). Several authors have suggested that in diabetes, telemedicine may be helpful to facilitate self-management, overcome the complex educational requirements, reduce costs, improve patient health-related quality of life (HRQoL), and obtain better outcomes (7,11–13). A meta-analysis of randomized controlled trials studying the use of telemedicine in the management of diabetes showed nonsignificant or a slightly significant decrease in HbA_{1c} (13–15). However, telemedicine did not affect patients' HRQoL, risk of hypoglycemia, or mortality in the short-term (13).

In the Spanish health care system, medical follow-up and ongoing intensive self-care for patients with type 1 diabetes are performed by endocrinologists in specialist care centers. Since in some regions of Spain not all care centers have an endocrinologist, telemedicine can play a key role in facilitating patients' follow-up. Telemedicine has emerged as a tool that can help optimize or facilitate the management of patients with type 1 diabetes living in rural areas or in places far from specialty care centers (16). Furthermore, telemedicine has been associated with time savings, cost savings, high appointment adherence rates, and high patient satisfaction (16). Earlier experiences of telemedicine in type 1 diabetes management suggested that its utilization is less costly and more efficient than face-to-face visits (17). In prior studies, monitoring glucose records and providing insulin dose adjustments using telemedicine systems proved effective in reducing HbA_{1c} in patients with poor glycemic control ($HbA_{1c} \geq 8\%$ [≥ 64 mmol/mol]) (3,6,7). A study conducted in rural pediatric patients with type 1 diabetes reported that telemedicine was not inferior to face-to-face care in controlling HbA_{1c}. Moreover, it showed that absenteeism from school and work by patients and caregivers decreased and that adherence to appointments was higher (18).

Although there is evidence of the clinical benefits of telemedicine in patients with type 1 diabetes and poor glycemic control, we have not found any randomized clinical trial assessing its impact in patients with type 1 diabetes and HbA_{1c} $<8\%$ (<64 mmol/mol). Therefore, the aim of this study was to assess the impact of the use of a telemedicine platform (Diabetic) for 6 months on patients with type 1 diabetes with acceptable metabolic control and treated with multiple daily injections, on clinical outcomes, patients' HRQoL, and physicians' satisfaction.

RESEARCH DESIGN AND METHODS

Study Design and Participants

We performed a randomized, 6-month follow-up, open-label, multicenter, parallel-group controlled study (PLATEDIAN; ClinicalTrials.gov identifier NCT03332472) involving the diabetes units of 10 hospitals in Andalusia (Spain).

All patients who attended their routine checkups in the diabetes units of participating hospitals from September 2014 to June 2016, and who met the inclusion criteria, were asked to participate in the study.

All participants received adequate information on the study and provided their written consent before the start of any procedures. The study protocol was approved by the ethics committee of Hospital Regional Universitario de Málaga. The study was conducted in accordance with the International Conference on Harmonization Guideline for Good Clinical Practice (19) and the Declaration of Helsinki (20).

Patients were included if they fulfilled the following inclusion criteria: 18–65 years of age, >2 years since type 1 diabetes diagnosis, HbA_{1c} levels $<8\%$ (<64 mmol/mol), multiple daily injection therapy with a basal-bolus regimen, resident in Andalusia, and patients who had signed the written consent form. Exclusion criteria included the use of continuous subcutaneous insulin infusion; patients with chronic kidney disease, liver disease, thyroid disease (except in the case of adequately treated and controlled hypothyroidism), type 2 diabetes, or severe psychological disorders; current participation in other clinical studies; and the digital gap (social inequality in the access and use of information technologies).

Randomization was performed using free, open source software, which generated a random number list and allocated the patients to each care delivery strategy. At the first visit (V1), eligible patients were randomized 1:1 by the investigator to either the intervention cohort (IC) or the control cohort (CC).

The research team at each participant hospital was composed of an endocrinologist and a diabetes specialist nurse. Endocrinologists and diabetes-specialized nurses from participating diabetes units were offered participation in the study.

Procedures/Interventions

For all participants, study follow-up was 6 months (24 weeks) and included one visit every 3 months. V1 and the final visit (V3) were face-to-face visits for both cohorts. The second visit (V2) was a face-to-face visit for the CC and a telemedicine visit for the IC (Supplementary Fig. 1). At the face-to-face visits, investigators collected all the study variables in a paper case report form (CRF). All patients used the same glucometer (BG-Star) to record glucose measurements.

During the study, participants were cared for only by the members of the site research team, regardless of the group to which they were assigned (CC or IC). So, they may be followed by an endocrinologist who was not the provider they normally saw.

CC

Patients in CC were followed up via face-to-face visits every 3 months (V1, V2, and V3). Study variables were collected, and insulin dose adjustments were made during each visit.

IC

Patients in IC were followed up via face-to-face visits at V1 and V3, whereas V2 was performed through a telemedicine visit at 3 months.

At V1, IC patients were trained by the research team nurse (who had expertise in the Diabetic platform) and received the necessary material to download glucometer data at home. Additionally, during the following 2 weeks, patients were asked to confirm that they could access the platform as well as contact researchers to resolve queries or report possible faults.

During the study (24 weeks), patients made free use of the platform, which allowed them to download their daily self-monitored blood glucose for charts and statistics. However, at V2 (3 months), the downloading of data was mandatory for these patients, and the research team accessed the Diabetic platform to review it and to adjust the insulin dose. The research team could contact patients via e-mail and mobile phone messages. No other telemedicine visits were performed at a time other than V2.

Diabetic

Diabetic is an Internet-based telemedicine system specifically designed for monitoring people with diabetes and helping patients and clinicians make decisions on disease management. The system has two versions of access: a web-based version, which allows patients access from their personal computer, and the mobile version, which allows access from their smartphones.

Patients can download their self-monitored blood glucose data stored in a glucometer (BG-Star or other glucometers). In the case of the BG-Star, data are downloaded through the web-based version of the platform, connecting the glucometer to the PC with a cable. Moreover, patients can include information regarding the insulin doses administered, the carbohydrates consumed, physical activity, and other health data.

The Diabetic platform generates charts, graphs, and statistics with data from capillary glucose measurements and the rest of the information collected on the platform, which is available for both patients and the research team. Patients can use the charts and graphs available on the platform to make decisions about their diabetes care. Physicians can evaluate the data available on the platform and obtain metabolic control statistics or treatment reports to manage the patients.

The Diabetic platform has been assessed in previous studies on telemedicine with successful outcomes (21).

Outcome Measures

The primary efficacy end point of the study was the mean change of HbA_{1c} levels from V1 to V3. Secondary efficacy end points included the change of mean blood glucose and glucose variability (SD, coefficient of glucose variation [CV = (SD/mean) × 100], and mean amplitude of glycemic excursions).

Other efficacy end points included patient-reported outcomes (PROs), assessed as the change in HRQoL scores and the change in the proportion of patients with a fear of hypoglycemia and with emotional distress.

HRQoL was determined using the Diabetes Quality of Life (DQoL) questionnaire that consists of 46 items divided into four subscale scores for *1*) satisfaction with treatment, *2*) impact of treatment, *3*) worry about the future effects of diabetes, and *4*) worry about social/vocational issues (22). Due to their closer relationship with a treatment change, only the subscales related to satisfaction with treatment and impact of treatment were assessed. Each subscale ranges from 0 to 100, with higher scores indicating better HRQoL.

To assess the emotional distress linked directly to diabetes, the Diabetes Distress Scale (DDS) questionnaire was used (23). The DDS consists of 17 items, which include four subscales: emotional burden, physician-related distress, regimen-related distress, and interpersonal distress. The total score ranges from 1 to 6, with higher values indicating greater distress ($\geq$3 reflects clinically meaningful distress levels).

The Fear of Hypoglycemia (FH-15) questionnaire assesses the fear of hypoglycemia in adult patients with type 1 diabetes (24). The test consists of 15 items using a 5-point Likert scale, and the sum of the responses indicates the overall score. In order to identify individuals with a fear of hypoglycemia who might benefit from psychological intervention, consideration was given to those who obtained a score of $\geq$28.

Internal reliability for DQoL, DDS, and FH-15 was previously established, and the Cronbach α coefficient for each questionnaire is available in Supplementary Table 1.

Secondary safety end points included the change in the number of events between V1 and V3 related to *1*) the frequency of severe hypoglycemia (requiring third-party assistance) in the 6 months prior to the visit, *2*) ketosis and diabetic ketoacidosis events, *3*) hospital admission due to decompensated glycemia, *4*) the frequency of mild hypoglycemia (symptomatic nonsevere hypoglycemia) in the 2 weeks prior to the visit, and *5*) hyperglycemia >250 mg/dL in the 2 weeks prior to the visit.

An ad hoc questionnaire was developed to assess physicians' satisfaction with the use of the Diabetic platform (Supplementary Table 2). It included a global satisfaction scale with scores between 1 and 10. Higher scores indicate greater satisfaction with the platform.

Data Collection

A CRF was developed to collect data at each visit. At V1, written consent was provided, eligibility criteria were verified, and patients were randomized and assigned to one of the two cohorts. Sociodemographic and clinical characteristics and efficacy and safety outcomes were reported. At V2, efficacy (except PROs) and safety outcomes and the use of resources (from V1 to V2) were collected on the CRF through the telemedicine visit (IC) or through the face-to-face visit (CC). At V3, clinical characteristics, efficacy and safety outcomes, and the use of resources (from V2 to V3) were collected on the CRF. At V3, physicians responsible for the IC patients completed a specific questionnaire to assess their satisfaction with the Diabetic platform.

Statistical Analysis

The sample size was calculated by assuming no inferiority criteria between cohorts (IC vs. CC) in the primary outcome, with 80% statistical power to detect intergroup differences of 0.4% (1.3% SD) (25) in the mean change in HbA_{1c} from baseline to the last visit after the 6-month follow-up, as reported previously. Given these assumptions, 167 patients per cohort were required. Taking into account a dropout rate of 15%, 192 patients were enrolled in each cohort.

Statistical analysis was based on all valid data of randomized patients who completed V1 and V3, according to per protocol analysis. In the descriptive analysis, absolute and relative frequencies were calculated to describe qualitative variables (sociodemographic characteristics and overall clinical characteristics).

Measures of centrality and dispersion (mean, SD, minimum, maximum, and quartiles) were calculated to describe the quantitative variables. The comparison of quantitative variables between cohorts was performed using the Student *t* test or the Mann-Whitney *U* test, depending on the results of the Shapiro-Wilk normality test. The χ^2 test was used to compare qualitative variables between cohorts.

Statistical analysis was performed using Stata version 14 (26).

RESULTS

A total of 388 adult patients with type 1 diabetes participated in the study, of whom 330 completed V1 and V3 and were therefore included in the analysis. Participants were randomized into the CC ($n = 167$) and the IC ($n = 163$) (Supplementary Fig. 1).

The baseline sociodemographic and overall clinical characteristics of the two cohorts are shown in Table 1. No statistical differences between cohorts were observed regarding sociodemographic and clinical variables at baseline.

No statistically significant differences were detected in relation to baseline characteristics (age, sex, HbA_{1c}, and % of patients in the intervention group) between the patients who withdrew from the study and the patients included in the analysis (Supplementary Table 2). The reasons for loss to follow-up are displayed in a CONSORT flow diagram (Supplementary Fig. 2).

Impact of Telemedicine on Efficacy and Safety End Points

Mean (±SD) HbA_{1c} remained similar to baseline after 6 months: 7.0 ± 0.7% (53.1 ± 8.1 mmol/mol) and 7.0 ± 0.8% (53.3 ± 8.3 mmol/mol) in the CC and IC, respectively. Thus, at the end of the study, the mean change in HbA_{1c} levels was similar in both cohorts: −0.04 ± 0.5% (−0.5 ± 5.8 mmol/mol) vs. 0.01 ± 0.6% (0.1 ± 6.0 mmol/mol) ($P = 0.4941$), respectively. The number of patients who achieved HbA_{1c} <7% (53 mmol/mol) was 73 (43.71%) and 78 (47.75%) in the CC and IC, respectively.

According to the glycemic variability, differences between SD, coefficient of variation, and mean amplitude of glycemic excursions values in the two cohorts were not significant ($P = 0.757$, $P = 0.746$, and $P = 0.436$, respectively).

At baseline, the number of weekly mild hypoglycemia episodes was significantly higher in the CC. The evaluation of the change from baseline of the number of episodes showed an increase of 0.34 in the IC and a decrease of 0.42 in the CC ($P < 0.05$). However, no significant differences were found in the number of hypoglycemias between the cohorts at 6 months. There were no significant differences in the other safety end points (Table 2).

Impact of Telemedicine on PROs

Table 3 shows the impact of telemedicine on PROs. Although there were significant differences in DQoL impact and satisfaction of treatment subscales between cohorts at the baseline, the assessment of change in HRQoL at V1–V3, using DQoL treatment subscales, did not differ between cohorts. Statistically significant differences were observed when comparing the proportion of patients with a fear of hypoglycemia (FH-15 ≥28) between the CC and IC at baseline and 6 months (V1: CC 54.6% vs. IC 40.8%, $P < 0.05$; V3: CC 58.7% vs. IC 40.2%, $P < 0.05$). No statistically significant differences were detected when comparing the proportion of patients with distress due to type 1 diabetes.

Physician Satisfaction

Physicians' satisfaction with the use of the Diabetic platform was moderate to high, with a mean score of 6.28 (on a scale of 0–10). More than 50% of the physicians

Table 1—Participant characteristics at baseline

	CC ($n = 167$)	IC ($n = 163$)	*P*
Age (years), mean (SD)	36.22 (10.78)	33.78 (9.77)	0.581
Female, *n* (%)	73 (43.7)	73 (44.8)	0.758
Marital status, *n* (%)			
Single	67 (40.1)	77 (47.2)	0.102
Relationship	24 (14.4)	26 (16.0)	
Married	67 (40.1)	54 (33.1)	
Divorced	8 (4.8)	4 (2.5)	
Widowed	1 (0.6)	2 (1.2)	
Education, *n* (%)			
Without studies	0 (0.0)	1 (0.6)	0.580
Primary education	32 (19.2)	13 (8.0)	
Secondary education	37 (22.2)	35 (21.5)	
Vocational education and training	39 (23.4)	50 (30.7)	
University studies	49 (23.3)	61 (37.4)	
Postgraduate studies	10 (6.0)	1 (0.6)	
Work, *n* (%)			
Employed	80 (47.9)	67 (41.1)	0.425
Self-employed	15 (9.0)	16 (9.8)	
Disability	5 (3.0)	0 (0.0)	
Student	17 (10.2)	32 (19.6)	
Unemployed	44 (26.4)	38 (23.3)	
Retired	3 (1.8)	2 (1.2)	
Household employed	2 (1.2)	1 (0.6)	
Other	1 (0.6)	3 (1.8)	
BMI (kg/m^2), mean (SD)	26.0 (4.6)	26.0 (4.6)	0.869
Weight (kg), mean (SD)	74.9 (15.7)	75.3 (15.4)	0.660
Height (cm), mean (SD)	169.1 (9.2)	170.8 (9.3)	0.414
Abdominal perimeter (cm), mean (SD)	87.3 (14.7)	86.8 (13.6)	0.683
Baseline HbA_{1c} (%), mean (SD)	7.1 (0.7)	7.0 (0.6)	0.317
HbA_{1c} <6.5% or <48 mmol/mol, *n* (%)	32 (19.2)	29 (17.8)	0.749
HbA_{1c} <7% or <53 mmol/mol, *n* (%)	68 (40.7)	66 (40.5)	0.966
CV >36%, % (*n*/*N*)	82.5 (52/63)	84.5 (60/71)	0.759
Glucose measurements/day, mean (SD)	3.9 (1.5)	3.8 (1.6)	0.406
Total cholesterol, mean (SD)	173.5 (27.0)	174.6 (29.4)	0.868
HDL, mean (SD)	63.9 (49.3)	59.7 (17.7)	0.692
LDL, mean (SD)	96.8 (22.9)	96.3 (25.4)	0.909
VLDL, Mean (SD)	14.1 (6.9)	19.6 (18.0)	0.895
Triglycerides, mean (SD)	78.0 (44.7)	90.8 (70.3)	0.422

CV, coefficient of glucose variation.

Table 2—Outcomes concerning safety variables

		CC ($n = 167$)	IC ($n = 163$)	P
Mild hypoglycemia/week, mean (SD)	V1	3.0 (3.0)	2.1 (2.1)	<0.05*
	V3	2.5 (2.4)	2.5 (2.2)	0.881
	Difference	−0.42	0.34	<0.05*
Severe hypoglycemia/3 months, mean (SD)	V1	0.2 (0.7)	0.1 (0.4)	0.116
	V3	0.1 (0.4)	0.1 (0.4)	0.825
	Difference	−0.12	0.00	0.136
Hyperglycemic episodes/week, mean (SD)	V1	2.3 (2.1)	2.4 (2.9)	0.391
	V3	2.1 (2.2)	2.4 (2.4)	0.098
	Difference	−0.20	0.09	0.110
Ketoacidosis/3 months, mean (SD)	V1	0.01 (0.08)	0.0 (0.0)	0.329
	V3	0.0 (0.0)	0.0 (0.0)	—
	Difference	−0.01	0.00	0.328
Hospital admissions for glycemic decompensation	V1	0.01 (0.1)	0.0 (0.0)	0.329
	V3	0.0 (0.0)	0.01 (0.1)	0.312
	Difference	−0.01	0.01	0.158

*P value <0.05.

were very or quite satisfied with metabolic control outcomes (54%), data accuracy (54.6%), data utility (52.7%), and platform flexibility (50.9%). Items with a lower satisfaction score were handling (43% very or quite satisfied), the speed of the platform (42.9%), and the improvement of adherence (43%).

CONCLUSIONS

Our study reveals that the clinical efficacy and safety outcomes obtained using telemedicine care for the management of type 1 diabetes and suboptimal HbA_{1c} (<8%) are similar to those obtained through face-to-face visits. Thus, the glycemic control in patients with type 1 diabetes with HbA_{1c} <8% (<64 mmol/mol) is similar in both cohorts at the end of the study. These results are in line with previous studies conducted in noncontrolled patients with type 1 diabetes ($HbA_{1c} \geq 8\%$ or ≥ 64 mmol/mol), which demonstrated improving HbA_{1c} without significant differences between the CC and the IC (15,27). Regarding adverse events, such as mild and severe hypoglycemia, hyperglycemic episodes, ketoacidosis, and the need for hospital admission, we did not find any differences between the two cohorts at 6 months. This supports previous results that reported that telemedicine did not reduce the risk of hypoglycemia and diabetic ketoacidosis (13,15).

Therefore, one of the main contributions of this study is to show that some face-to-face visits may be replaced by telemedicine visits on the routine clinical care of patients with type 1 diabetes and acceptable metabolic control. One of the most important benefits of telemedicine is its ability to improve access to health care. Telemedicine offers an alternative to patients that live in geographically or socioeconomically isolated communities, far from medical facilities, or those with limited mobility. Previous studies had also demonstrated the effectiveness of telemedicine in delivering diabetes care to patients in rural areas (15,16,28). The reduction of face-to-face visits is especially important in cases with low health care resources and difficulties getting access to the endocrinology medical center, as in some areas of Andalusia. On the other hand, telemedicine care involves infrastructure requirements, technological skills, and the engagement of health care professional and patients. This fact could condition the incorporation of telemedicine into routine clinical practice in the care of patients with type 1 diabetes.

The fear of hypoglycemia is associated with a reduction in insulin use, increased energy intake (15), and poor metabolic control. Despite the randomization, there is a higher percentage of patients with a fear of hypoglycemia in the CC, both at baseline and at 6 months. Since there is no significant change in the fear of hypoglycemia in either cohort, it may be concluded that the fear of hypoglycemia does not respond to the care delivery strategy but likely to particular psychological strategies. Moreover, the HRQoL subscales evaluated did not change during the 6-month follow-up, suggesting that the telemedicine intervention does not impair the patients' lifestyle.

A few clinical studies have assessed health care provider satisfaction with telemedicine systems in the management of patients with type 1 diabetes. Physicians' satisfaction could be a key factor for implementing and improving this telemedicine system. Despite the positive overall satisfaction score assigned by the physicians, some aspects related to treatment adherence and related to the digital platform characteristics, such as its handling and its speed, should be refined.

To our knowledge, this is the first randomized study that focuses on patients with type 1 diabetes and acceptable metabolic control, using a large sample size and a follow-up period of 6 months. One of the main strengths of this study is its randomized and multicentric design. This design allows the inclusion of a larger number of subjects from different locations within the region, contributing to the generalization of the results. Moreover, the assessment of psychosocial factors and PROs provides information concerning the impact of the disease on patients' lives that may complement and support other objective findings.

Nevertheless, this study has some limitations. First, the duration of type 1 diabetes was not collected at baseline. This may be one of the main limitations of the study,

Table 3—PROs for both cohorts

		CC ($n = 167$)	IC ($n = 163$)	P
Fear of hypoglycemia: FH-15 score ≥28 (%)	V1	54.6	40.8	<0.05*
	V3	58.7	40.2	<0.05*
Stress related to diabetes: DDS score ≥3 (%)	V1	32.9	27.6	0.276
	V3	29.9	24.5	0.256
HRQoL: DQoL score (satisfaction), mean (SD)	V1	67.8 (16.1)	72.0 (12.4)	<0.05*
	V3	69.5 (16.3)	71.7 (14.8)	0.215
	Difference	1.72	−0.37	0.313
HRQoL: DQoL score (impact of treatment), mean (SD)	V1	75.1 (13.2)	78.7 (10.7)	<0.05*
	V3	75.6 (12.4)	79.0 (10.9)	<0.05*
	Difference	0.58	0.26	0.957

*P value <0.05.

since the duration of the disease may have an impact on its clinical management. Second, data of mild hypoglycemia were collected only 2 weeks prior to baseline and V3, thus limiting the generalization of the results. Third, glucose variability was assessed using capillary blood glucose measurements instead of continuous glucose monitoring. However, a study demonstrated that glycemic variability parameters calculated with four capillary blood glucose measurements in children with type 1 diabetes had a good correlation with those estimated with data from continuous glucose monitoring (29). Fourth, the internal reliability of the physicians' satisfaction questionnaire used in the study has not been psychometrically tested. The questionnaire was specifically designed for this study by Sanofi to assess physicians' satisfaction with the use of the Diabetic platform and has not been used or assessed in previous studies. Finally, since diabetes is a long-term condition requiring continuity of care, health interventions should be assessed for a long period of time. Our findings suggest a similar impact on clinical outcomes between groups; however, additional studies with a longer follow-up period are needed to confirm these results and shed light on this topic.

In conclusion, the results of the study show that, compared with routine care, the use of telemedicine has a similar impact on glycemic control, episodes of acute diabetes-related complications, and quality of life. Therefore, the study allows us to prove the advantages of this innovative care option in the usual follow-up of this specific profile of people with type 1 diabetes and shows that telemedicine may improve patient access to health care and diabetes management in some geographic areas.

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