TELEASSISTANCE IN PATIENTS WITH TYPE 1 DIABETES DURING COVID-19 PANDEMIC: RESULTS FROM A PILOT STUDY

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Table of Contents

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Abstract

Background: Telemedicine in chronic disease management has received a significant boost during the health emergency from COVID-19.

Objective: We have evaluated the effectiveness of two virtual visits on glycemic control parameters in patients with type 1 diabetes (T1D) during the lockdown period.

Methods: Among the T1D patients who had scheduled an office visit during the lockdown (n=211), those who made two virtual visits (baseline and follow up) (n=166) were enrolled for the present study. Time in range (TIR), time above and below range, mean daily glucose, glucose management indicator (GMI), and coefficient of variation were compared between the two visits.

Results: TIR significantly increased from 62?18 % to 64?17 % (p=0.02) in all patients, and more markedly in patients using the meter (N=11, baseline TIR 55±17 % and follow-up TIR 66±13 %, p=0.01) and with baseline GMI ?7.5 % (N=45, baseline TIR 45±15 % and follow-up TIR 53±18 %, p=0.0001). The only variable independently associated with TIR increase was the change of therapy while the sensor type and insulin delivery systems did not influence glucometric parameters.

Conclusions: These findings demonstrate that the structured virtual visits allow the persistence and the improvement of glycemic control in situations where the office visit is not feasible. Clinical Trial: This study does not meet the criteria of a clinical trial

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TELEASSISTANCE IN PATIENTS WITH TYPE 1 DIABETES DURING COVID-19 PANDEMIC: RESULTS FROM A PILOT STUDY

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Abstract

Background: Telemedicine in chronic disease management has received a significant boost during the health emergency from COVID-19. Diabetes and technologies supporting diabetes care as devices monitoring glucose, software analyzing glucose data, and systems delivering insulin are examples of how it is possible to develop remote and structured disease management. Indeed, most of the currently available technologies store and transfer data on the web to be shared with health care providers.

Objective: During this devastating pandemic, we have decided to offer our patients the opportunity to manage diabetes remotely by implementing technology. Therefore, we have designed our research with the aim to evaluate the effectiveness of two virtual visits on glycemic control parameters in patients with type 1 diabetes (T1D) during the lockdown period.

Methods: This is a prospective observational study, including T1D patients who completed two virtual visits during the lockdown for COVID-19. The glucose outcomes evaluating the benefit of the virtual contact were time in range (TIR), time above and below range, mean daily glucose, glucose management indicator (GMI), and glycemic variability. This metric was generated by specific computer programs that automatically upload data from the devices used to monitor blood or interstitial glucose. If needed, we changed ongoing treatment at the first virtual visit.

Results: Among 209 eligible T1D patients, 166 completed two virtual visits, 35 failed to download glucose data, and 8 refused the visit. Among patients not included in the study, there was a significantly lower prevalence of continuous glucose monitoring (CGM) and continuous subcutaneous insulin infusion (CSII) users (CGM, 16 vs. 93%; CSII 21 vs. 77%; $p=0.0001$) compared with patients who completed the study. TIR significantly increased from the first to the second virtual visit: first visit 62±18 %, second visit 64±17 % ($p=0.02$). The increase in TIR was more marked in patients using the traditional meter (N=11, baseline TIR 55±17 % and follow-up TIR 66±13 %, $p=0.01$) compared with patients using CGM, and in patients with baseline GMI ≥7.5 % (N=45, baseline TIR 45±15 % and follow-up TIR 53±18 %, $p=0.0001$) compared with patients with

GMI <7.5%. The only variable independently associated with TIR was the change of ongoing therapy. The unstandardized beta coefficient and [95% CI] were 5 [0.7-8], p=0.02. The type of glucose monitoring and insulin delivery systems did not influence glucometric parameters.

Conclusions: These findings demonstrate that the structured virtual visits allow the persistence and the improvement of glycemic control in situations where the office visit is not feasible.

KEYWORDS: Tele-assistance; Type 1 diabetes, COVID-19; Time in range; Technology.

Introduction

Background

The recent pandemic by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has caused restricted access to medical clinics to prevent the risk of infection. In this context, routine care for patients with chronic diseases as diabetes has become a big challenge. Several strategies have been implemented, supporting patients with Type 1 (T1D) and Type 2 diabetes (T2D) during the SARS CoV-2 pandemic and providing adequate assistance to avoid the worsening of the disease [1-4]. Patients with diabetes have been recommended to follow general guidance on infection risk reduction, monitor blood glucose, take pills, inject insulin and non-insulin drugs adequately, and maintain a healthy lifestyle (diet and physical activity) [5].

Furthermore, experts have also strongly suggested implementing the download of glucose data by dedicated software and sharing information with the health care provider to facilitate any kind of remote assistance [6]. More in general, the efficacy of virtual visits by phone calls, text messages, mobile phone app, or computer-based visits, outside the context of the current pandemic, has been described in some studies and systematic reviews. Evidences are not univocal, and text messages seem to be more effective than web-based interventions [7-10]. Despite the number of published papers reporting consensus on video-consultation and guidelines for managing diabetes in the COVID-19 (COronaVIrus Disease 19) setting, there is no prospective evidence about the efficacy of tele-assistance as an alternative to the ambulatory visit during COVID-19 pandemic [1,2,5,6]. Indeed, most of the papers, with a relevant number of patients, are retrospective and have analyzed remotely data thanks to the specific software downloading glucose data without contacting the patients.

Aim and Hypothesis

As a virtue of necessity, we have implemented remote medical examinations of patients with type 1 diabetes during the lockdown period (March 10th - June 3rd). In the current paper, we report on new glucometric parameters collected during two different virtual visits. We have hypothesized that the COVID-19 pandemic might affect metabolic control in patients with diabetes due to access limitation to the diabetes care center and poor compliance to adequate lifestyle. We have accordingly designed a pilot study to prospectively analyze the effectiveness of two structured virtual visits (video consultation or phone contact) on the time spent in target range (TIR), the time spent above and below the target range (TBR, TAR), mean daily glucose, glucose management indicator (GMI), and glycemic variability [11].

Methods

Patients

Our pilot study is a prospective single arm observational study, including T1D patients who completed two virtual visits (baseline and follow-up) from the start (March 10th) to the end (June 3rd) of the lockdown. The protocol was preliminary submitted and approved by the local Ethical Committee 'Regione Calabria, Area Centro', 79-2020. Three diabetes care centers at teaching hospitals were involved in the research. A nurse or physician contacted the patients by phone before the first virtual visit (first contact), explaining the study's purpose. Patients who gave verbal consent were enrolled. Baseline characteristics of patients who refused to participate in the study were collected and compared to those of patients who accepted to participate. During the phone call, patients were informed about or instructed, if necessary, on how to download the data from continuous glucose monitoring (CGM) system or the traditional meter into the cloud using specific software, as Clarity, Care Link, Eversense DMS, Accu-chek DMS (diabetes management system), and share the data through the cloud or send by email. They were also invited to send recent laboratory tests or reports from other specialists by email or by mobile phone Apps. Patients using traditional meters were strongly suggested to check blood glucose before each meal and in the presence of symptoms suggestive of hypoglycemia. During the second contact (baseline virtual visit), the physician verified the clinical conditions, the ongoing treatment, and the adherence to a healthy lifestyle. Blood glucose data were commented on, and treatment changed accordingly. The second virtual follow-up visit (third contact) was planned by clinical conditions and glycemic control and completed as the baseline visit. All information collected during the virtual visit were uploaded into the electronic medical files and the summary of the visit sent by email.

Data Collection

For the present analysis, the following parameters were collected: TIR, time spent below target range (TBR), time spent above the target range (TAR), mean daily glucose, and standard deviation (SD) referred to the two weeks before the baseline and follow-up visit. The coefficient of variation (CV), an estimate of glycemic variability, and the glucose management indicator (GMI), an estimate of glycated hemoglobin, were calculated according to the following formulas if not automatically generated by the software analyzing glucose data: CV= [(SD/Mean Glucose)*100]; GMI= (3.38+0.02345*Mean glucose) [12].

Statistical Analyses

Statistical analyses were performed by SPPS 23 for Macintosh. Patients who did not agree to participate or complete two virtual visits were excluded from the analyses. For the statistical analyses, patients were divided into groups: those included and excluded from the study; those using the sensor and injecting insulin by pump [CGM+CSII (Continuous Subcutaneous Insulin Infusion)]; those using the sensor and in Multiple Daily Insulin Injection [CGM+MDI]; those testing blood glucose by traditional meter (Self-Monitoring Blood Glucose SMBG) and injecting insulin by pump or in MDI [CSII or MDI+SMBG]. Sensor users included patients using intermittently scanned CGM (isCGM) and real-time CGM (rtCGM). Variables not normally distributed were baseline mean daily glucose, GMI, and TBR. Parametric and non-parametric tests were applied accordingly.

The *t*-test for unpaired data and the Mann-Whitney U test were used to compare differences between groups. The *t*-test for paired data and the Wilcoxon Signed-Rank test were used to compare variables between baseline and follow-up visits. The chi-square test was applied to compare percentages (CGM or sensor use and MDI or CSII treatment) between groups. The multivariable regression analysis was performed to evaluate variables independently associated with the absolute difference of TIR between baseline and follow-up visits. Independent variables included in the model were age, disease duration, use of the sensor or pump, and therapy change. The absolute difference of TIR, calculated as TIR at follow-up - TIR at baseline visit, was not normally distributed and, therefore, log-transformed before applying the regression analysis.

Results

Characteristics of patients

Two-hundred-nine patients were scheduled for office visits during the lockdown, from March 10th to June 3rd. Forty-three patients (20%) refused to participate in the study. Among these, thirty-five (17%) stated difficulties to download or send data by email, and eight (4%) did not accept the virtual visit. The remaining 166 (79%) were enrolled and analyzed. The average mean interval between the two virtual visits was 11 weeks. Characteristics of patients included and excluded from the study have been reported in Table 1. The prevalence of CGM and CSII users was significantly higher in patients included in the analyses. In detail, among 166 patients, 11 (7%) were testing blood glucose with SMBG; 20 (12%) were using the isCGM; 135 were using rtCGM (81%). Among excluded patients, only 7 (20%) were using CGM, while the remaining 28 (80%) were using SMBG. All patients monitoring blood glucose by traditional meter were using the Accu-Chek Connect DMS. All the patients included in the study had strips and sensors to monitor glucose during the lockdown. The mean number of tests per day in those performing SMBG was 4.4±1.9 at baseline and 5.1±2.4 at follow-up visit (p=0.21), and the mean number of scans per day in those using isCGM was 9.5±4.9 and 9.8±6.1 (p=0.7).

Glucometric characteristics at baseline and follow-up visit

We have compared glucometric parameters, collected at the baseline and the follow-up visit, in all patients included in the study and patients divided according to different combinations of insulin delivery methods and glucose monitoring systems (3 groups: CSII+CGM; MDI+CGM; CSII or MDI+SMBG) (Table 2). TIR significantly increased from baseline to follow-up visit in all T1D patients and in the CSII or MDI plus SMBG group. CSII or MDI plus SMBG patients also had a significant improvement of TAR, mean daily glucose, and GMI compared with the other groups. CV also significantly increased in these patients.

When we divided all patients included in the study according to the baseline GMI, we found TIR significantly improved in those with GMI≥7.5% (N=46; 45±15 % vs 53±18 %; p=0.0001) compared with patients with GMI<7.5 % (N=120; 68±15 % vs 69±15 %; p=0.98).

One-hundred-four patients (63%) were suggested to change therapy during the baseline visit. Among these, 97 (93%) were using the CGM (isCGM or rtCGM), and 84 (81%) were on CSII. The prevalence was comparable to that of patients who did not change therapy (CGM 93%, p=0.60; CSII 71% p=0.10). The absolute difference of TIR between baseline and follow-up visits was significantly higher (p=0.04) in patients who changed therapy (4±10 %) than the difference in those who did not change therapy (0.1±10 %). No statistically significant difference was detected between the two groups in TBR, TAR, mean daily glucose, CV and GMI (data not shown).

None of the patients had diabetic ketoacidosis or severe hypoglycemia requiring hospitalization in the interval between two virtual visits.

The multivariable regression analysis revealed the change of therapy as the only variable independently associated with absolute TIR difference between baseline and follow-up visits. The unstandardized beta coefficient and [95% CI] were 5 [0.7-8], p=0.02.

Discussion

Principal Results

Our study demonstrates that the structured virtual visit maintains a pre-existing good glycemic control or improves the time spent in the target range in subjects with T1D during an emergency when the office visit is not permitted.

The benefit of virtual visit was noticeable in patients using the traditional meter regardless of the type of insulin deliver (MDI or CSII) and in patients with baseline GMI ≥7.5%. These results suggest some considerations. The phone call preceding the baseline virtual visit may have encouraged patients performing SMBG to download data from the meter into the diabetes management systems facilitating the following interpretation of glucose data. It is common in real life that patients performing SMBG do not bring the meter along on the office visit or do not have devices connecting to the cloud, limiting the appropriate adjustment of treatment. Patients using SMBG had higher values of GMI and lower TIR, despite not statistically significant, than sensor users, which may have induced physicians to strengthen more the general suggestions for diabetes management and convince patients to keep a healthy lifestyle rather than change therapy. It might be argued that the new metrics have been developed for glucose data collected by the sensor and that the results we found in our study in patients using the traditional meter might be due to chance. However, we have recently demonstrated that a strict correlation between TIR calculated by specific software, after downloading SMBG values, is significantly correlated with HbA1c. The strength of the relationship we found in our study was comparable to that between TIR calculated from CGM and HbA1c reported in other studies [13]. Patients using the meter showed a significant increase in CV compared to the other groups. This result is likely explained by higher daily fluctuation in SMBG patients compared to CGM users. Indeed, at the follow-up visit, mean glucose decreased -11%, and CV increased 2.9%. That might be an unfavorable result, if sustained, in the long term. Some of the above considerations also apply to patients using CGM who did have not had a worsening of glycemic control during the lockdown for COVID-19.

Patients with GMI ≥7.5 % may have better-managed diabetes during pandemic and had an appropriate lifestyle. We believe patients generally have had much more time available, forced home by the restriction measures. That may have stimulated a more in-depth analysis of glycemic data and possibly intervention on incorrect habits.

Patients using the sensor or wearing the pump did not experience any worsening of glucose metrics during the lockdown. In our opinion, this is to be considered an excellent outcome, given the current emergency. Sensor and pump users are in general well-educated and motivated to check and self-manage the disease. It is noteworthy that the pump and sensor users' prevalence was very low in patients excluded from the study. The main reason limiting the recruitment of patients was trouble in downloading glucose data.

The multivariable regression analysis revealed the change of therapy during the virtual visit as the only variable independently associated with the absolute difference in TIR. Insulin therapy can be safely changed during a structured virtual visit. Indeed, none of the patients included in the tele-assistance had a severe hypoglycemic episode or ketoacidosis.

Our results reinforce the evidence that virtual communication may lead to appropriate care during a pandemic or when an in-person visit cannot be performed for any reason.

Comparison with prior works

Recent case studies have demonstrated that tele-assistance can be used safely and effectively for new-onset type 1 diabetes and ketoacidosis, avoiding admission into the hospital [14,15].

A retrospective study, including 13 adolescent patients with T1D, has demonstrated that physical activity regularly performed during lockdown associated with improvement of TIR [16]. Unfortunately, we did not collect information about physical activity in our sample. However, we can hypothesize that patients included in our study stayed active at home in some way.

Another retrospective analysis, including 92 patients with T1D using the CGM systems, has demonstrated a TIR increase from 59 to 63% during the lockdown. The research was performed reviewing glucose values downloaded into the cloud [17]. Similarly, a smaller study, including 33 patients with T1D using the isCGM system connected to the clinic, has demonstrated a TIR increase from 54 to 65% during the lockdown. In this article, it is not mentioned if a virtual contact was proposed during the lockdown [18].

We would like to remark on the potential educational role of virtual assistance. Indeed, a training session on the pump and sensor use and carbo-counting can be scheduled by specialists as nutritionists or nurses, favoring the access to technologies despite the physical distancing [19].

There are still open questions about tele-assistance, including cost, reimbursement, authorization, liability, characteristics of people to be engaged, choice of the method to perform the virtual visit, the involvement of the health care provider, duration of the visit, and adequate time interval between visits [20]. It is also essential to identify patients who need face-to-face visits despite an emergency as the current pandemic. Finally, we should not forget patients with type 2 diabetes represent the majority of patients with diabetes and, in general, have limited access to technology and are less educated to self-manage diabetes. Likely, we should pursue different strategies in T2D.

Conclusion

Our prospective study demonstrates the effectiveness of tele-assistance in managing disease during the lockdown for COVID-19. Data sharing and remote visit allow for maintaining or achieving good glycemic control through data analyses and therapeutic adjustment. The study has some limitations: the groups of different therapeutic strategies are relatively small. Patients with T1D, who constitute the minority of patients with diabetes, frequently adopt personalized insulin delivery schedules and monitoring systems. It is therefore difficult to have large homogeneous groups. It is possible that well-educated patients were more likely to give their consent to the virtual visits. That makes the results of this study certainly more reliable for patients who have received a good therapeutic education and are cooperative. Ultimately the selection criteria were arbitrary, but they were chosen to include the largest number of patients, and we are therefore confident that can be applicable to most of our patients with type 1 diabetes.

In conclusion, we can state that the COVID-19 restrictions offered the opportunity to bring tele-assistance in the frontline of diabetes care. The advancement of technology and the development of new connected devices will further facilitate information exchange between patients, health care providers, and physicians.

Conflict of Interest

There is no Conflict of interest for each of the authors participating in the research.

Abbreviation

isCGM: Intermittently scanned continuous glucose monitoring

rtCGM: real-time continuous glucose monitoring

COVID-19: COronaVIrus Disease 19

CSII: continuous subcutaneous insulin infusion

CV: coefficient of variation

DMS: diabetes management system

GMI: glucose management indicator

MDI: multiple daily insulin injection

SARS-CoV-2: severe acute respiratory syndrome coronavirus-2

SMBG: self-monitoring blood glucose

T1D: type 1 diabetes

T2D: type 2 diabetes

TAR: time above range

TBR: time below range

TIR: time in range

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Table 1: Characteristics of patients with Type 1 diabetes included and excluded from the analyses.

Variables	Patients included	Patients excluded
Number	166	43
Age (years)	40±14	37±15
Male (%)	48	49
Disease duration (years)	20±11	17±9
SMBG (N/%)	11/7*	36/84
CGM (isCGM + rtCGM) (N/%)	155/93*	7/16
MDI (N/%)	38/23*	34/79
CSII (N/%)	128/77*	9/21

SMBG: self-monitoring blood glucose; isCGM: intermittently scanned continuous glucose monitoring; rtCGM: real-time continuous glucose monitoring; MDI: multiple daily insulin injection; CSII: continuous subcutaneous insulin infusion; Data are expressed as mean±standard deviation, and percentage. *p=0.0001.

Table 2: Glucometric parameters at the baseline and the follow-up virtual visit in all patients and patients divided according to the insulin delivery method and the glucose monitoring system.

	All (N=166)	CSII + CGM (N=122)	MDI + CGM (N=33)	CSII or MDI + SMBG (N=11)
TIR (%)				
Baseline	62±18	63±17	62±19	55±17
Follow-up	65±16	65±17	64±17	66±13
p-value	***0.02***	*0.24*	*0.19*	***0.01***
TBR (%)				
Baseline	3.5±4.1	3.2±4.0	4.4±4.3	4.7±4.0
Follow-up	3.4±3.8	3.1±3.7	3.7±3.3	5.8±5.0
p-value	*0.58*	*0.86*	*0.34*	*0.33*
TAR (%)				
Baseline	34±18	34±18	33±21	40±18
Follow-up	32±18	33±18	32±18	28±15
p-value	*0.08*	*0.40*	*0.52*	***0.03***
Mean daily glucose (%)				
Baseline	163±29	162±25	162±37	176±49
Follow-up	159±25	161±24	157±26	150±25
p-value	*0.25*	*0.90*	*0.17*	***0.04***
CV (%)				
Baseline	34±6	34±6	36±7	36±8
Follow-up	34±7	33±7	35±7	42±9
p-value	*0.32*	*0.93*	*0.55*	***0.04***
GMI (%)				
Baseline	7.2±0.7	7.2±0.6	7.2±0.8	7.5±1.1
Follow-up	7.1±0.6	7.1±0.6	7.0±0.6	6.9±0.6
p-value	*0.23*	*0.90*	*0.12*	***0.04***

TIR: time in range; TBR: time below range; TAR: time above range; CV: coefficient of variation; GMI: glucose management indicator; CSII: continuous subcutaneous insulin infusion; CGM: continuous glucose monitoring; MDI: multiple daily insulin injection; SMBG: self-monitoring blood glucose; Data are expressed as mean±standard deviation. *p-value* in the table is referred to the comparison between paired data.

Supplementary Files