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# Interactive Diary for Diabetes: A Useful and Easy-to-Use New Telemedicine System to Support the Decision-Making Process in Type 1 Diabetes

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## Abstract

***Background:*** Widespread use of carbohydrate (CHO) counting is limited by its complex educational needs, but a telemedicine system could simplify the patients' training.
***Methods:*** The Diabetes Interactive Diary (DID) was set up on patients' mobile phones and allowed to record the blood glucose values and quantify the total CHO intake during a meal, by choosing the specific food and the amount ingested from a list of pictures. It also suggested the most appropriate insulin bolus in relation to the patient's CHO/insulin ratio. Data were sent to the physician by Short Message Service (also known as text message). Two pilot studies were carried out to investigate the feasibility and acceptability of the system and its effectiveness in improving metabolic control.
***Results:*** In the first study, 50 patients were involved in a survey with questionnaires administered before and 12 weeks after the start of the DID. The system was considered by almost all the patients as easy to use and very helpful. CHO counting and insulin bolus calculation were ranked as the most useful functions. In the second study, 41 consecutive patients using DID under routine clinical practice conditions were evaluated after a median of 9 months of follow-up. DID was associated with a nonstatistically significant reduction in fasting blood glucose (FBG), postprandial glucose (PPG), and hemoglobin A1c levels. FBG and PPG coefficient of variation (CV) values were significantly reduced: FBG-CV decreased by 6.7% (95% confidence interval −11.9, −1.6; $P = 0.02$), while PPG-CV decreased by 11.5% (95% confidence interval −19.3, −3.7; $P = 0.01$). No patients reported serious hypoglycemic episodes requiring medical intervention.
***Conclusions:*** DID can represent a useful, safe, and easy-to-use tool to help the patient with type 1 diabetes promote dietary freedom. Adjustment of insulin doses according to CHO intake allowed the reduction of glucose variability, increasingly recognized as an important, independent risk factor for cardiovascular events.

## Introduction

Results from the Diabetes Control and Complications Trial[1] and U.K. Prospective Diabetes Study[2] convincingly demonstrated the importance of tight glycemic control in preventing complications. According to American Diabetes Association recommendations,[3] this requires not only self-monitored blood glucose testing and hemoglobin A1c (HbA1c) monitoring, but also a process and system by which nutritional care and the specific lifestyle recommendations are provided for individuals with diabetes, involving patients in the decision-making process (medical nutrition therapy).[4] Several studies have shown that medical nutrition therapy and specific diet-related behaviors result in a decrease of 0.25–1.0% in HbA1c in patients with diabetes.[5–8]

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In individuals receiving intensive insulin therapy, the total amount of carbohydrates (CHOs) in the meal did not influence the glycemic response if the pre-meal insulin was adjusted for the CHO content of the meal.[8–12] Starting from this observation, structured training designed to maintain glucose control while enabling dietary freedom can be effective in promoting dietary freedom, quality of life, and glycemic control, without increasing severe hypoglycemia or cardiovascular risk.[13]

Nevertheless, the balancing of CHO intake and insulin dose is not easy to obtain, as the patient has to be educated with respect to knowledge of CHO-containing food, evaluation of weight and serving of meals, and estimation of the right amount of preprandial insulin according to a specific and individual insulin/CHO ratio.[7]

Given the complexity of such an educational approach, the use of telemedicine can be an important tool for patients to communicate with their physician.[14] An interactive diary can help them identify the appropriate insulin dose according to the amount of CHO ingested, while avoiding the use of difficult calculations.

We tested whether the "Diabetes Interactive Diary" (DID) could help type 1 diabetes management by combining a telemedicine tool with interactive instruction, dietary guidance, and calculation tools, while avoiding complex educational interventions. Two pilot observational studies were carried out to investigate the feasibility and acceptability of the system and its effectiveness on metabolic control improvement.

## Research Design and Methods

### *DID system*

The DID is a CHO/insulin bolus calculator, an information technology, and a telemedicine system based on the communication between the health care professional (physician or dietician) and the patient via Short Message Service (SMS) (also known as text message) (Fig. 1). The system is able to guide the patient in the management of diet, physical activity, and more appropriate bolus insulin calculation. In addition, it also includes an algorithm for the calculation of basal insulin dose, based on the value of fasting blood glucose (FBG) and the presence of hypoglycemic episodes.

This software is set up on a mobile telephone, which can thus be used as a small computer to record the blood glucose values and dose of insulin injections real-time; furthermore, the system is also able to suggest the daily CHO intake, by summing the amount of CHO ingested during the day. Every patient can decide what to eat during the meal by choosing among all the food listed in the software. The quantification of the total calories and CHO ingested is facilitated by a list of pictures showing the specific food and the portion chosen.

The DID allows the automatic calculation of the insulin dose and suggests modifications, based on the CHO/insulin ratio and the glycemic correction factor, identified and prescribed by the health care professional, together with other information recorded by the patient (e.g., food chosen, blood glucose level, physical activity, etc.). The use of the DID for

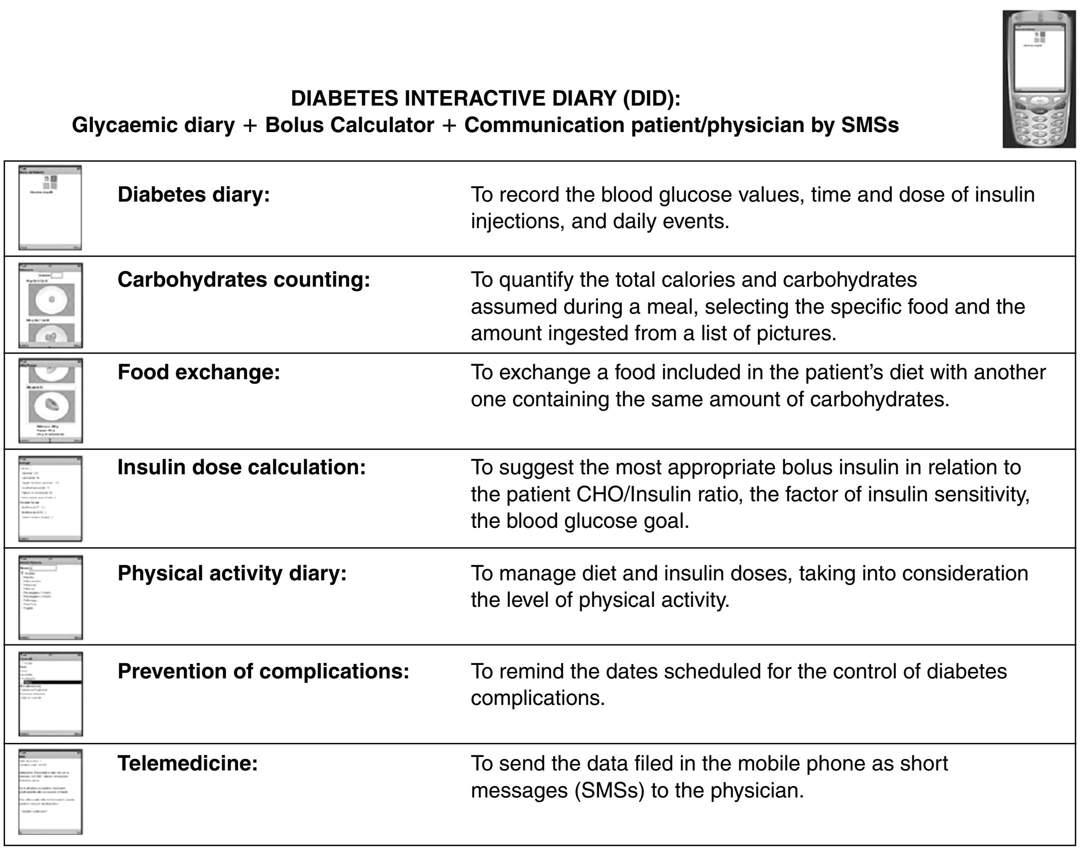


**FIG. 1.** DID: glycemic diary + bolus calculator + communication between patient and physician by SMS messages.

data collection on diet, physical activity, and insulin intake is associated with an immediate feedback for the patient, in terms of therapeutic and behavioral advice. Furthermore, the data filed on the mobile phone can be sent as short SMS messages, improving the communication between patients and health care professionals.

### *DID 1 (pilot study to investigate feasibility and acceptability)*

DID 1 aimed to evaluate the feasibility and acceptability of the system. The study involved four Italian diabetes outpatient clinics. They were asked to enroll 50 patients with type 1 diabetes, between 18 and 65 years old, treated with multiple injections of short-acting and long-acting or NPH insulin analogues or with continuous subcutaneous insulin infusion; patients practiced self-monitoring of blood glucose at least three times a day. All the patients were requested to give written informed consent to gain entrance to the study. Moreover, other important requirements in the selection of patients were an adequate familiarity in the use of mobile phones, according to the physician's judgment, and the possession of a personal SIM card.

Exclusion criteria were HbA1c levels >11.0%, pregnancy, severe concomitant diseases, and illiteracy or inability to comply with the study requirements.

All the patients received a structured intensive training about the software functioning before starting the study. Educational sessions were provided by a physician and/or nurse.

Patient satisfaction with the telemedicine system was investigated through specifically developed questionnaires: a pre-study questionnaire containing 13 items on the expectations about the system; a post-study questionnaire containing 17 items on the acceptability of the system; and a specific-use questionnaire containing 11 items on technical and practical issues related to the use of the DID. Questionnaires were administered at study entry and after 12 weeks. Sociodemographic and clinical data were also collected. Measurements of body weight, blood pressure, and HbA1c were performed at baseline and after 12 weeks. Additional information was collected at the end of the study, including the number of contacts between the patient and the diabetes specialist (both SMS messages and office visits) and any serious hypoglycemic episode requiring medical intervention. Finally, the frequency of the physician's reply to SMS messages was evaluated. Baseline and end-of-study treatment satisfaction and general health status were investigated using the World Health Organization-Diabetes Treatment Satisfaction Questionnaire (WHO-DTSQ) and the SF-36 Health Survey Instrument.[15–19]

Statistical analysis. The primary end point of the study was represented by the percentage of patients who used the DID successfully and declared they were satisfied with it. Additional end points were the differences between end-of-study and baseline levels of HbA1c, blood pressure, body mass index (BMI), and SF-36 and WHO-DTSQ scores.

Population characteristics and questionnaires' results are reported as mean and standard deviation for continuous variables and frequencies and percentages for categorical ones. HbA1c, blood pressure, and BMI mean levels and SF-36 and DTSQ scores at baseline and after 12 weeks were compared using the Wilcoxon test.

### *DID 2 (pilot study to investigate effectiveness on metabolic control)*

DID 2 aimed to evaluate the effectiveness of the system on metabolic control. A cohort of 41 consecutive patients, who were prescribed the DID as an integral component of their diabetes care, was identified from the electronic database of one of the four centers participating in DID 1. Clinical data routinely registered in the period of time falling between the visit immediately preceding the start of DID use and the last visit before data extraction were used for the analysis.

Statistical analysis. Population characteristics are reported as mean and 95% confidence intervals for continuous variables and frequencies and percentages for categorical ones. Pre–post comparisons with respect to DID initiation were performed for the following parameters: mean levels of HbA1c, FBG, and postprandial glucose (PPG), FBG and PPG coefficient of variation (CV) values, and mean short-acting and long-acting insulin units. To this purpose, a repeated-measures linear regression analysis was performed. An autoregression and spatial-power structure were used to account for within-measures correlation and with unequally spaced time occasions.

## Results

### *DID 1*

Overall, 50 individuals were recruited: 48.9% were men, mean age was 33.2 ± 8.9 years, and mean duration of diabetes was 13.9 ± 9.5 years. Of the patients, 57% were treated with multiple injections of insulin and 43% with continuous subcutaneous insulin infusion. Mean levels of HbA1c were 7.2 ± 0.8%. Most of the patients (91.7%) had at least 13 years of school education (college degree).

The pre-study test investigated the patients' expectations about the system. Overall, 96% of the patients rated the idea of an interactive diary as "excellent" (44%) or "good" (52%), while 98% were interested in trying the DID; 72% of the patients thought that an interactive diary could be "extremely helpful" or "very helpful" for diabetes management. Patients were also asked which functions of an interactive diary could be more important to help them manage their diabetes. The availability of an insulin bolus calculator (31%), the possibility to communicate more easily with the doctor (23%), and the availability of a CHO counting system (19%) were the features considered more interesting by the participants.

The post-study questionnaires investigated the satisfaction of the patients with the use of the telemedicine system. Overall, the DID was judged as "excellent" or "good" by 94% of the patients, "extremely useful" or "very useful" by 65% of them, and "very easy" or "somewhat easy" to use by 90%. Furthermore, the set-up process was considered easy by 96.8% of the patients, and instructions were rated "excellent" or "good" by 79.6% of them.

Patients were also asked to rank the different functions of the DID from the most useful to least useful. The function considered as the most useful was CHO counting (mean rank

1.7 ± 1.0), followed by insulin bolus calculation (mean rank 2.3 ± 1.5), food diary (mean rank 2.7 ± 1.1), physical activity diary (mean rank 3.7 ± 1.3), and food exchange (mean rank 3.7 ± 1.4).

Over 63% of the patients declared that the DID had changed their eating habits, thanks to a greater knowledge of the relation among food, blood glucose, and insulin dose.

During the study, the DID system was regularly used by the participants. In particular, information on CHO content of the meals was requested on average (± SD) 3.1 ± 1.5 times a day, blood glucose values were recorded 4.8 ± 2.3 times a day, and advice on insulin dose was obtained 3.2 ± 1.3 times a day.

Communication with the doctor by SMS messages was rated as "extremely effective" or "very effective" by 85.5% of the patients. The average number of SMS messages sent by each patient during the study was 10.4 ± 3.1, while the average number of SMS messages sent by physician in reply was 10.0 ± 3.4. That is, patients almost weekly sent a SMS to their physician, and physicians regularly replied to confirm the therapeutic scheme or to modify the parameters (CHO/insulin ratio, insulin sensitivity factor, and/or blood glucose goal). In terms of costs for the patient, assuming a cost of 10–15 Euro cents per message, and considering that on average each patient sent 10 SMS messages, the overall cost sustained did not exceed 1.5 Euros.

The main limits of the system pointed out by some of the patients were the slowness of the software and the lack of some food in the list and pictures.

As for clinical aspects, no significant variations were shown between baseline and end-of-study data, either with respect to clinical parameters (HbA1c, blood pressure, BMI) or in DTSQ-WHO and SF-36 scores. No patients reported serious hypoglycemic episodes requiring medical intervention during the study.

In addition, a stratified analysis by center was performed (data not shown). Results obtained from the different centers were superimposable, thus suggesting that patients' judgments were not influenced by differences in the educational approach adopted by the four participating centers and/or different levels of investigators' motivation.

### *DID 2*

Mean age of the 41 participating patients was 31.6 ± 11.9 years, while the mean duration of diabetes was 9.5 ± 7.6 years; 61.0% of the patients were male. Baseline mean levels of HbA1c, FBG, and PPG were 7.6%, 147.9 mg/dL, and 149.2 mg/dL, respectively (Table 1). After a median follow-up of 9 months from the DID initiation, FBG decreased by 9.7 mg/dL ($P = 0.09$), PPG by 14.7 mg/dL ($P = 0.13$), and HbA1c by 0.33% ($P = 0.27$). Both FBG and PPG CV values were significantly reduced: FBG-CV decreased by 6.7% ($P = 0.02$), while PPG-CV decreased by 11.5% ($P = 0.01$). During the study, the mean daily dose of short-acting insulin decreased by 0.3 IU ($P = 0.13$), while the mean long-acting insulin dose increased by 2.5 IU ($P = 0.045$). No patient dropped out from the study. No patients reported serious hypoglycemic episodes requiring medical intervention.

## Conclusions

The complexity of the educational approach needed to teach CHO counting can represent an obstacle for many patients, thus limiting the possibility of its widespread use as an effective self-management tool. Our data show that the DID can represent a useful tool, incorporating several features that can help the patient to promote dietary freedom. Using the CHO/insulin bolus calculator coupled with information technology and a telemedicine system based on SMS messages, the patient can easily adjust insulin doses, based on CHO intake, without a deeper knowledge of the complexities of CHO counting.

The first pilot study showed that the system is well accepted by the patients and easy to set up on the mobile phone, a familiar technology already used in the daily life by most individuals. The DID met the expectations of patients, a vast majority of whom found it very useful to help them manage their diabetes. It is interesting to note that the CHO counting and the insulin bolus calculator were considered by the participants as the most useful features contained in the software. It was also deemed by many as an important educational tool to better understand the complex relationship among CHO intake, blood glucose levels, and insulin dose needed. At the present time, a paper diary represents the most common tool for data communication between the patient and his or her diabetologist, but often it is not adequately filled in, or, even if sufficiently complete, it cannot induce a day-by-day adjustment of the insulin dose and lifestyle.[20] By allowing the automatic storage of blood glucose measurements, CHO intake, and insulin doses, DID facilitated the collection of relevant data, easily communicated to the physician through SMS, thus improving the exchange of information between patient and provider. On the

Table 1. Baseline Patients' Characteristics and Their Changes over 9 Months

| | *Mean (95% confidence interval)* | | |
|---|---|---|---|
| | *Baseline* | *Change* | P |
| HbA1c (%) | 7.6 (7.3–7.9) | −0.33 (−0.77, 0.11) | 0.27 |
| FBG (mg/dL) | 147.9 (138.2–157.6) | −9.7 (−20.4, 1.1) | 0.09 |
| PPG (mg/dL) | 149.2 (138.2–160.2) | −14.7 (−33.3, 4.0) | 0.13 |
| FBG-CV (%) | 40.8 (37.4–44.1) | −6.7 (−11.9, −1.6) | 0.01 |
| PPG-CV (%) | 39.5 (33.2–45.8) | −11.5 (−19.3, −3.7) | 0.01 |
| Dose of insulin (IU) | | | |
| Short-acting | 20.0 (17.2–22.8) | −0. (−4.8, −4.2) | 0.13 |
| Long-acting | 22.1 (20.6–23.7) | 2.5 (0.4, 4.6) | 0.045 |

other hand, the requirement of using the system for regular communication with the physician did not negatively impact quality of life.

The second pilot study tested the effectiveness of the system under routine clinical practice conditions. The study showed that, although statistical significance was not reached, after 9 months use of the DID was associated with a reduction in FBG, PPG, and HbA1c levels. These findings deserve consideration in the light of the rather satisfactory levels of metabolic control of the study patients at baseline. Therefore, it could be hypothesized that greater benefits could be obtained in patients with poorer metabolic control. In addition, 95% confidence intervals do not exclude the possibility of a larger benefit; this remains to be proved in a larger study.

Importantly, FBG and PPG variability values were significantly reduced. In particular, postprandial glycemic variability was decreased by one-third, thus suggesting that use of the DID can be important in tailoring insulin doses on the basis of the CHO content of the meals. Glucose variability and postprandial hyperglycemia are increasingly recognized as important, independent risk factors for cardiovascular events.[21,22] The adjustment of insulin doses according to CHO intake greatly increases the chance of reducing postprandial blood glucose peaks, thus also minimizing the risk of large glucose excursions. It is also noteworthy that the positive impact on blood glucose profile was obtained with minimal changes in the total dose of insulin administered and was not associated with an increased risk of hypoglycaemia, demonstrating the safety of the DID system.

Some limitations of these studies need to be discussed. First, they are not randomized controlled trials, and the lack of a control group can represent a weakness of the study design. Nevertheless, it should be underlined that the two pilot studies represented only the first step, necessary to establish the acceptability and safety of the system. These studies also gave preliminary hints on the possible benefits, mainly related to lower glycemic variability.

The second limitation is related to the possibility that the impact on metabolic parameters be a "trial effect," associated with more frequent patient–physician interactions, rather than a net effect of the DID system. Nevertheless, we believe that the coherent reductions in HbA1c, FBG, PPG, and glucose variability are promising and deserve attention. Two ongoing randomized clinical trials will specifically evaluate the impact of the DID system on metabolic control and glycemic variability, using different glucose fluctuations indices.

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## Author Disclosure Statement

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