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ORIGINAL ARTICLE

The Impact of a Clinical Decision Support System in Diabetes Primary Care Patients in a Developing Country

Júnia Xavier Maia, MD,[1] Lidiane Aparecida Pereira de Sousa, PhD,[1]
Milena Soriano Marcolino, MD, PhD,[1,2] Clareci Silva Cardoso, PhD,[1,3]
José Luiz Padilha da Silva, PhD,[4] Maria Beatriz Moreira Alkmim, MD, MSc,[1,2]
and Antonio Luiz Pinho Ribeiro, MD, PhD[1,2]

Abstract

Background: Telehealth strategies have the potential to improve diabetes care, but there is a lack of evidence about the impact of these strategies in developing countries. Our objective was to analyze the feasibility, usability, and clinical impact of a decision support system (DSS) in Brazilian primary care diabetes patients.
Materials and Methods: This was a quasi-experimental study that included type 2 diabetes primary care patients >40 years of age. Patients were assessed before (during 6 months) and after the implementation of the DSS application (4 months). The DSS application, used by health professionals, included clinical evaluations and blood glucose measurements and generated specific recommendations based on the data entered.
Results: In total, 145 patients were included (mean age, 62.0 ± 9.9 years), 62.1% were female, and 70.0% had been diagnosed with diabetes more than 5 years ago. Overall, there was no decrease in median hemoglobin A1c (HbA1c), from 7.7% (range, 6.5–9.8%) to 7.4% (range, 6.5–9.2%) (P for slope = 0.347). Subgroup analysis showed that patients with an HbA1c level of ≥9% at baseline had a significant reduction in median HbA1c level, from 10.5% (range, 9.9–11.3%) to 10.0% (range, 8.9–10.9%) (P for difference of slope between subgroups = 0.004). The reduction occurred in the first phase of the study, before the DSS use. Healthcare practitioners considered the DSS easy to use (99%) and believed that it provided useful information for patient care (100%).
Conclusions: In this study the improvement of glycemic control before the application in more decompensated patients (HbA1c ≥9%) probably reflects the systematization of diabetes care. The DSS use did not improve the HbA1c level, possibly because of the short follow-up and/or infrequent use by the healthcare practitioners.

Background

The increasing worldwide prevalence of diabetes mellitus is a global concern. In Brazil, around 12 million people have diabetes, corresponding to about 8.7% of the population.[1] As a chronic condition, it requires continued and appropriate health care to prevent acute and long-term complications. The complexity of diabetes care demands a multifactorial strategy, and telehealth can be an important aspect of this strategy.

Tehehealth systems have been used to receive, organize, and send information about diabetes patients, such as clinical and laboratory data.[2] Many authors have noted that telehealth, as an adjunct to the care of diabetes, is feasible and noninferior to usual care.[3–9] In a systematic review and meta-analysis conducted by our group, telemedicine use resulted in

[1]Telehealth Network of Minas Gerais, Belo Horizonte, Minas Gerais, Brazil.
[2]Medical School and Clinical Hospital, Federal University of Minas Gerais, Minas Gerais, Belo Horizonte, Brazil.
[3]Federal University of São João Del-Rey, Divinópolis, Minas Gerais, Brazil.
[4]Department of Statistics, Federal University of Minas Gerais, Belo Horizonte, Minas Gerais, Brazil.
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a significant and clinically relevant reduction in glycohemoglobin levels.[10] Most of the studies included in the meta-analysis[10] were performed in developed countries, so there is lack of evidence about the impact of telehealth strategies in diabetes patients in developing countries. The objective of this study is to analyze the feasibility, usability, and clinical impact of a decision support system (DSS) in Brazilian primary care diabetes patients.

Materials and Methods

This was a quasi-experimental study that included diabetes patients being followed in the primary care settings of six cities attended by the Telehealth Network of Minas Gerais, a public telehealth service.[11] At the time this study was conducted, the Telehealth Network of Minas Gerais covered 660 cities in the state, performing teleconsultations in different specialties and telediagnosis in cardiology.

A state region was chosen by lot. After this, six cities in this region were randomly selected using the exclusion criteria of a mean of fewer than two teleconsultations per city per month in the last 6 months and/or refusal of the primary care nurse (who would be the local study coordinator) or the local health manager to participate. The cities had a median population of 5,150 inhabitants, ranging from 2,800 to 11,000.

Application and clinical DSS development and operation

Three endocrinologists, an epidemiologist, and a family physician, along with the information technology staff, were responsible for the DSS planning and development. The software was developed as an application (app), to be used in tablets by healthcare professionals during office visits of type 2 diabetes patients. It included four clinical modules: initial evaluation, subsequent evaluations, capillary blood glucose measurements, and feet assessments.

The initial and subsequent assessments contained a list of questions regarding the patient's general condition and a segment for storage of laboratory test results, with the latter including fields for hemoglobin A1c (HbA1c), blood glucose, and other routine laboratory tests in diabetes. The module for evaluation of the diabetic foot contained questions about foot inspection and systematic screening examinations for neuropathic and vascular involvement.

The DSS app generates specific recommendations based on the data entered, including calculation and classification into categories of body mass index, calculation of estimated glomerular filtration rate and alerts in cases of advanced renal failure, warnings about poor glycemic control with suggestions of possible adjustments, a table with capillary blood glucose measurements, recommendations for reassessment of medication doses in cases of doses above the maximum, recommendations for prescription of aspirin and statins to patients not using these medications, recommendation of metformin use, recommendations about proper selection of antihypertensive medications for diabetes patients with hypertension, and recommendations for screening for microvascular complications of diabetes.

The clinical team performed internal tests and adjustments, and field-testing was performed by primary care professionals of the Telehealth Network of Minas Gerais.

Patients

As the app was planned for individuals with type 2 diabetes, the inclusion criteria for patients were as follows: age >40 years old; having diabetes treated with any oral antidiabetes drug (metformin, sulfonylureas, dipeptidyl peptidase-4 inhibitors, or others), combined or not with insulin use; acceptance to participate in the study; and the signing of an informed consent form.

A primary care nurse was selected in each of the six cities for local coordination of the study. This professional was responsible for informing all other primary care nurses and physicians in the city about the research project and for inviting them to participate. The participating professionals were instructed to select all the consecutive diabetes patients they attended who met the inclusion criteria until completing a sample of 25 patients per city (totaling 150 patients). All participant professionals were trained by the research team. Patients were recruited from August to October 2012.

This study was approved by the research ethics committee of the Universidade Federal de Minas Gerais. Nurses, physicians, local health managers, and patients signed an informed consent form.

Experimental design

In the first phase (baseline), patients underwent the clinical assessment usually performed by the primary care physicians (usual care). The researchers did not interfere in the frequency of patient visits or medical treatment. Data on duration of diabetes, comorbidities and complications, medication use, physical examination, capillary blood glucose, and laboratory testing were recorded, and HbA1c was measured at 0, 4, and 6 months. At 6 months, low-density lipoprotein cholesterol and creatinine (in order to allow the calculation of the patient's estimated glomerular filtration rate) were also measured.

In the second phase, the app was introduced as part of the care of the diabetes patients. Each participating professional received a tablet with a 3G Internet connection, a login, and a password. They were instructed to use the app during all visits, consultations, or capillary blood glucose measurements. During this phase, which lasted for 4 months, the software utilization was regularly monitored, as part of the research protocol. Professionals who were not using it were contacted by telephone calls. HbA1c and low-density lipoprotein cholesterol levels were measured at the end of this phase, 10 months after the first measurement.

The method used for measuring HbA1c followed international recommendations[12] and is standardized by the National Glycohemoglobin Standardization Program.[13]

Participant professionals were instructed to insert in the app results of other tests performed in the cities and possibly related to diabetes such as fasting glucose levels, triglyceride levels, and microalbuminuria.

Statistical analysis

Descriptive statistics were used to characterize the data. To address missing values in HbA1c measurements, the procedure of multiple imputation by chained equations (MICE) was used.[14] Each missing value was imputed 20 times considering a linear model for HbA1c and assuming the data were missing at random. Final results were combined using the rules of Rubin.[15] In relation to HbA1c, a subgroup analysis was performed according to the HbA1c level on enrollment: ≥9% versus lower threshold values. Subsequently, a generalized estimated equation (GEE) method with an exchangeable correlation structure was used to examine whether there was statistical significance in the overall slope and whether there were differences in the longitudinal trend of HbA1c between the two subgroups. For all results, $P < 0.05$ was considered significant. All analyses were conducted in the statistical software R version 3.1.0[16] using the core package as well as the MICE and GEE packages.

Usability assessment

At the end of the study, a standardized questionnaire was administered, in order to evaluate the usability. The questionnaire contained 13 multiple choice questions, involving habits and frequency of Internet access, as well as impressions about ease of use, usefulness, and applicability of the recommendations generated by the app. At the end of each question there was a field for open comments. This field also existed for general comments at the end of the questionnaire.

Results

The total number of diabetes patients included in the study was 148. Three patients were excluded for not having any HbA1c level measured, so the study population was 145 patients. Three cities included 25 patients, two cities 24 patients, and one city 22 patients. Table 1 shows the characteristics of patients included in the study.

There was great variability in the frequency of app usage among cities. The total number of initial assessments inserted in the app was 111, resulting in an average of 18.5 per city; the remaining 34 patients were included without an initial evaluation. The number of subsequent evaluations inserted in the app was 254, averaging 42.3 per city.

Table 1. Clinical and Demographic Characteristics of the 145 Type 2 Diabetes Patients Included in the Study

Variable	Value
Age (years)	62.0 ± 9.9
Female (%)	62.1
Time since diabetes diagnoses (%)	
<1 year	0.9
1–5 years	28.8
5–10 years	23.4
10–20 years	39.6
>20 years	7.2
Comorbidities (%)	
Hypertension	61.4
Dyslipidemia	26.9
BMI (kg/m^2)	29.0 ± 5.2
Blood pressure (mm Hg)	
Before phase	
Systolic	126.0 (20.0)
Diastolic	80.0 (10.0)
After phase	
Systolic	130.0 (20.0)
Diastolic	80.0 (20.0)
Chronic complications (%)	
Retinopathy	2.7
Neuropathy	4.5
Nephropathy	6.3
Diabetic foot	2.7
Amputation due to diabetes	1.8
Stroke	2.7
Myocardial infarction	3.5

Data are expressed as mean ± SD values, median value (interquartile interval), or percentage, as indicated.

BMI, body mass index.

Capillary blood glucose

The number of capillary blood glucose measurements inserted in the app was 808. The number of values of the phase before the app (paper forms) was 702. There was a significant variation among cities in the number of measurements recorded in the app: from 45 to 297 per city.

Medications in use

The use of commonly prescribed medications by study patients was assessed. The number and percentage of patients using basal insulins (NPH, insulin glargine, and insulin detemir), respectively, at the beginning and end of the study ranged from 33 (22.7%) to 36 (24.8%). These numbers and percentages for short- or rapid-acting insulins (regular, insulin lispro, insulin aspart, and insulin glulisine) were four (2.7%) to seven (4.8%), for metformin were 103 (71.0%) to 102 (70.3%), for aspirin were 50 (34.5%) to 58 (40.0%), for statins were 40 (27.6%) to 49 (33.7%), and for angiotensin-converting enzyme inhibitors and/or angiotensin II receptor blockers were 82 (56.6%) to 86 (59.3%).

Foot evaluation

One hundred nineteen feet examinations were evaluated in the app (mean of 19.8 per city and 0.82 per patient). Ninety-seven (81.5%) had normal findings, and 22 (18.5%) had abnormal findings. The main causes of abnormal evaluations were altered protective sensation ($n = 11$, 9.2%), signs of previous ulceration ($n = 10$, 8.4%), absent posterior tibial and/or dorsalis pedis pulses ($n = 5$, 4.2%), and current ulceration ($n = 3$, 2.5%). The total percentage exceeds 100% because some patients had more than one abnormality.

Results of intensified monitoring

The frequency of app usage before and after intensified monitoring was assessed. Of the total 1.292 utilizations, 482 occurred in the preceding 2 months versus 810 in the 2 months following the intensification.

HbA1c values

At first, the HbA1c values were described overall over time. Subsequently, patients were divided into two groups: Group 1 consisted of patients with HbA1c ≥9% on enrollment, and Group 2 patients included those with values <9%. The results are shown in Table 2 as median values. Mean HbA1c values decreased from 10.8 ± 1.3% to 9.8 ± 1.7% ($P < 0.001$) in the subgroup with baseline HbA1c ≥9% and remained stable in the subgroup with HbA1c <9% (7.0 ± 1.0% vs. 7.0 ± 1.1%; $P = 0.597$).

Table 2. Hemoglobin A1c Values over Time

Time point[a]	*Total group* (n = *145*)	*HbA1c*	
		≥9%	*<9%*
Time 1	7.7 (6.5–9.9)	10.5 (9.9–11.3)	6.9 (6.3–7.7)
Time 2	7.5 (6.4–8.8)	9.9 (8.6–11.2)	7.1 (6.3–7.8)
Time 3	7.6 (6.6–9.3)	10.2 (8.7–11.3)	6.9 (6.4–8.1)
Time 4	7.4 (6.6–9.3)	10.0 (8.9–10.9)	7.0 (6.3–7.6)

Data are expressed as median (interquartile interval).
[a]Times 1–3 occurred before the decision support system use, and Time 4 occurred after the decision support system use.
HbA1c, hemoglobin A1c.

The fitted GEE model assumed time, group, and interaction effects. A significant value of interaction coefficient allowed us to conclude that the slopes are not equal, indicating that the rate of decrease in HbA1c level was different between the groups ($P = 0.004$). Those individuals with baseline ≥9% had more marked reduction compared with those with initial values below this threshold, as is shown in Figure 1. It should be noted, however, that the significant drop happened between time points 1 and 2, before introduction of the app.

Usability

In total, 24 professionals, including physicians and nurses, used the system. Use was higher by nurses (16 professionals) than by physicians (eight professionals), and 12 (10 nurses and two doctors) responded to the questionnaire. Results are presented in Table 3.

Most professionals considered the app useful to systematize and organize the care for diabetes patients, and several of them started using the recommendations of the DSS to also treat other diabetes patients not included in the study. Most professionals had no difficulty with the use of technology; some reported some initial insecurity that resolved after getting used to the procedures. In open comments at the end of the questionnaire, the absence of electronic medical records in most primary care units has been identified as an obstacle to the definitive incorporation of the app into the work routine.

It was not possible to determine how many patients were referred for screening of diabetic nephropathy and ophthalmological evaluation, but some nurses reported in the questionnaires an increase of such assessments and greater incorporation of them into the routine care of patients with diabetes. All nurses in the study reported an increased frequency and systematization of diabetic foot evaluation in the cities.

Discussion

This study, performed in Brazilian primary care diabetes patients, showed that the implementation of a DSS is feasible in this context. Included patients were representative of a population with type 2 diabetes treated in primary care regarding age, body mass index, and frequency of comorbidities. The app was tested in remote Brazilian cities with low Internet connectivity, showing satisfactory results in terms of usability.

Regarding HbA1c, data from four collections were presented, with the intervention (app) performed between samples 3 and 4. In the overall analysis no significant difference was found. However, subgroup analysis showed a significant reduction from time point 1 to time point 2 in patients with HbA1c levels ≥9% on enrollment, that is, during data collection on paper forms in the first phase of the study, before the DSS use. Previous studies[10] demonstrated greater impact of telehealth interventions in those with uncontrolled diabetes. It is possible that the improvement observed in the present study may be attributed more to the organization and systematization of care,[17,18] required for the introduction of the app, than to the use of the DSS.

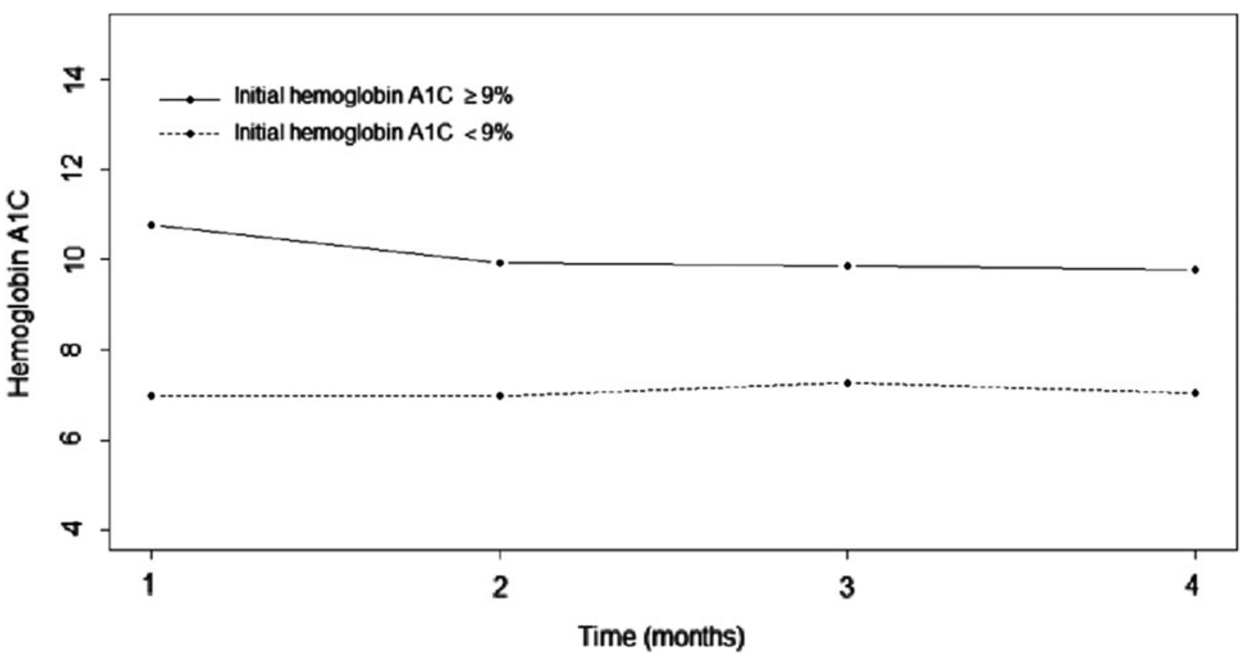

FIG. 1. Evolution of hemoglobin A1c level by baseline group.

TABLE 3. ANSWERS TO THE HEALTHCARE PROFESSIONAL QUESTIONNAIRE EVALUATING THE APPLICATION

Question, answer	*Percentage*
Ease of use of the application	
Very easy	8%
Easy	92%
Usefulness for the care of diabetes patients	
Very useful	58%
Useful	42%
Facility of incorporation to the work routine	
Easy to incorporate	75%
More or less easy to incorporate	25%
Implementation of the DSS recommendations in the treatment of patients	
Have implemented many recommendations	66%
Have implemented some recommendations	17%
Have implemented few recommendations	17%
Recommendation of the application to a colleague	
Certainly would recommend	58%
Would recommend	42%

DSS, decision support system.

Given that changes in HbA1c reflect average blood glucose over the last 30–120 days and that the length of study follow-up was short, little or no impact on this variable was already predicted.

The possibility of a sharper impact on other measures was expected, such as assessments of complications and prescription of adjuvant treatment medications, such as aspirin and statins. These drugs, which are part of the overall approach of the diabetes patient, are often underused.[19] The proportion of patients on statins increased from 27.6% to 33.7%, and that of aspirin users increased from 34.5% to 40%. It was not possible to analyze the statistical significance of this result, but in the questionnaires some professionals reported an impression of increased prescription of these drugs by the physicians involved in the study.

Overall, the frequency of DDS use was low, and nurses showed greater adherence to app usage than physicians. Frequently nurses filled in the data, generated the alerts, and passed along the recommendations on drug therapy so that the patient's physician could assess the indication of prescription changes. The major limiting factors to a greater usage in this study were the difficulty in incorporating the app into the healthcare practitioners' daily routine, as they needed to fill in data in duplicate because of the absence of an electronic medical record, as well as work overload. In addition, the low number of capillary blood glucose measurements reflects a common practice in Brazilian primary care: glucose meters are not universally available, strips are costly, and occasionally health professionals do not encourage patients to measure blood glucose levels more often. We also believe that many tests have probably not been entered in the app. A more frequent use of the app by the entire multidisciplinary team could probably achieve greater clinical impact than what is currently observed.

Despite evidence of positive impact in glycemic control in individuals with diabetes,[10] telehealth still remains underused because of factors such as absence of specific regulation in many countries, lack of reimbursement, difficult incorporation into the work routine, and professional resistance.[20] In this study the utilization of the app increased significantly after the adoption of a more intensified monitoring strategy by more frequent telephone contacts in the cities.

All professionals who answered the final questionnaire considered the app "easy" or "very easy" to use and "useful" or "very useful" for the care of diabetes patients. There is a risk of bias in this result because not all professionals participating in the study were able to attend the final meeting, when the questionnaires were administered. Those who were absent were requested to send their evaluation by e-mail, which did not occur in some cases.

Among other limitations of the study we should mention its duration. As changes in HbA1c levels occur at between 1 and 3 months of an intervention, the ideal would be for each phase to have lasted at least 6 months. Also, the use of the app more frequently by nurses than by physicians may have reduced the impact of the intervention because in Brazil changes in prescriptions, ordering of laboratory tests, and referrals to specialists are made almost exclusively by physicians. Finally, the lack of health system information technology in small cities is an obstacle for the accurate assessment of changes in prescription and process indicators, such as the number of patient referrals to specialties like endocrinology, nephrology, and ophthalmology.

Conclusions

This study showed that the implementation of a DSS to support the management of diabetes patients in primary care is feasible and that healthcare practitioners considered it to be useful. Improvement in glycemic control of the patients with uncontrolled diabetes observed in this study occurred in the phase before the app use and may reflect an effect of greater organization and systematization of the care. The lack of improvement during DSS use may have occurred by the limitations of the study, especially the short duration (which reduces the impact on HbA1c) and underutilization of the app by health professionals.

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Author Disclosure Statement

No competing financial interests exist.

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Address correspondence to:
Júnia Xavier Maia, MD
360 Geraldo Lúcio Vasconcelos Street
30.575-859, Belo Horizonte, MG, Brazil

E-mail: xaviermaia@yahoo.com.br