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ORIGINAL ARTICLE

Cost-Effective Use of Telemedicine and Self-Monitoring of Blood Glucose via Diabetes Tele Management System (DTMS) to Achieve Target Glycosylated Hemoglobin Values Without Serious Symptomatic Hypoglycemia in 1,000 Subjects with Type 2 Diabetes Mellitus—A Retrospective Study

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Abstract

Objective: This study assessed the effectiveness, safety, and costs of the Diabetes Tele Management System (DTMS®; Dr. Jothydev Kesavadev, Jothydev's Diabetes and Research Center, Kerala, India)-based health care in type 2 diabetes (T2D) patients in South India.

Research Design and Methods: We conducted a retrospective cohort study using electronic health records in our Center. The study sample comprised T2D patients enrolled in DTMS-based management, 30–75 years old, eligible for a glycosylated hemoglobin (HbA1c) target <6.5% and actively participating in various components of DTMS such as regular reporting of self-monitoring of blood glucose (SMBG) values and dose adjustments via telemedicine. We analyzed HbA1c, lipid profile, and other parameters measured at the first visit and on subsequent physical visits at months 3 and 6 and estimated the incidence of hypoglycemia.

Results: We analyzed records of 1,000 subjects with 6-month follow-up data (mean age, 53.2±9.8 years; 64% male). Patients had an average of 17±2 telemedicine follow-ups and reported 66,745 SMBG values over 6 months. The mean±SD HbA1c value was 8.5±1.4% at the initial visit and was reduced to 6.3±0.6% at 6 months ($P<0.0001$). The rate of SMBG values <70 mg/dL was approximately 0.04/patient/month, with 84% patients reporting no hypoglycemia. The recurring extra cost to patient for DTMS, not considering cost of oral drugs and insulin, was equivalent to 9.66 U.S. dollars/month.

Conclusions: DTMS, based on telemedicine follow-up and multidisciplinary care with SMBG-based monitoring, appears to be safe and cost-effective in the intensive treatment of T2D without serious co-morbidities. This system also avoids limitations of a traditional health care such as the need for very frequent physical visits for each and every drug dose adjustment, diet, and exercise advice.

Background

Self-monitoring of blood glucose (SMBG) is of proven benefit in type 1 diabetes. In type 2 diabetes (T2D), its benefit has been questioned in some studies, whereas in insulin-requiring patients it is regarded as a useful guide to the success of therapy.[1] Current guidelines advocate a target level of glycosylated hemoglobin (HbA1c) of 7% or below and even stricter control in select cases without serious cardiovascular and other co-morbidities. The American Diabetes Association advocates a target HbA1c below 6.5% in individual subjects under good care with no serious co-morbid illnesses.[2] Milestone clinical trials like the Diabetes Control and Complications Trial[3] and the United Kingdom Prospective Diabetes Study[4] have also proven the benefits of intensive glycemic control in preventing microvascular complications of diabetes. It has been suggested that well-structured SMBG data may prompt primary care physicians to intervene earlier and more effectively.[3] However, strict control is often not reached in primary health

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practice because of factors related to both the physicians and patients.[5]

For instance, many physicians do not intensify diabetes treatment in a timely manner in suitable patients.[6] A major barrier hindering the achievement of a glycemic goal is the physician's fear of hypoglycemia. Success in treatment of T2D patients is also hindered by patient-related factors such as cost of treatment, nonadherence to instructions, fear of hypoglycemia, fear of adverse effects due to drugs, poor disease awareness, and lack of motivation. We frequently encounter patients who own a glucometer yet do not use it regularly. We also see patients who come in for medical advice only once every few months with just one set of fasting blood sugar/post-breakfast blood sugar values at a time. Such patients end up treated inadequately for fear of hypoglycemia that could occur with strict control. Patients also frequently show poor compliance with prescribed medicines. A telemedicine-based approach based on SMBG and regular contacts with a multidisciplinary healthcare team is a possible approach to tackle many of the above-mentioned barriers. The Diabetes Tele Management System (DTMS®; Dr. Jothydev Kesavadev, Jothydev's Diabetes and Research Center, Kerala, India) since 1999 is a possible solution to achieve targets in diabetes control overcoming the major barriers.[7]

Components of DTMS

Team. In DTMS, a trained group of physicians, diabetes educators, dieticians, nurses, pharmacists, and psychologists is involved in patient care. For this study, there were three physicians (diabetologists), four diabetes educators, two diabetes nurses, three dieticians, two pharmacists, and one psychologist from the center.

SMBG and HbA1c. Conventionally, T2D patients in India visit laboratories once in a while to measure fasting and post-breakfast blood sugar values. HbA1c measurements are not done for the vast majority of patients under usual care. All treatment decisions are based on occasional fasting and post-breakfast values. This practice might be particularly unsatisfactory because the cultural practice in many places in India is to have major meals at lunch and dinner.

The relative contribution of postprandial glucose excursions to average sugar levels are significant in fairly well controlled diabetes, whereas the contribution of fasting hyperglycemia to HbA1c increases gradually with increasing levels of HbA1c.[8] Postprandial measurements have additional clinical significance because they are attributed to adverse cardiovascular outcomes.[9] Here, because the patients were not having major co-morbid illnesses, postprandial blood sugar levels were considered for tight glycemic control. Also, more postprandial measurements in T2D patients would offer the opportunity to better assess glycemic control and make adjustments in treatment and dietary habits. Considering all these factors, postmeal sugars were taken into consideration in DTMS. T2D patients are required to practice SMBG and report four-point blood glucose measurements (fasting, 2-h postprandial values after each main meal, 3:00 a.m., and other values whenever required) to the Center on a regular basis, with frequency individualized according to clinical status. Occasional 3 a.m. values are also monitored to consider the possibilities of nocturnal hypoglycemia, the dawn phenomenon, and the Somogyi phenomenon, which enable reduced risk of hypoglycemia while targeting optimal fasting blood sugar values. HbA1c values are monitored on physical visits.

Electronic health records. The DTMS team maintains a log of reported values in electronic databases, which are used to monitor glycemic control and modifies doses of insulin and oral hypoglycemic agents (OHAs) as necessary. Adjustments are not based on any algorithm; rather, the team takes into consideration a multitude of details maintained in the DTMS software, such as duration of diabetes, age of patient, presence of co-morbidities, past incidence of hypoglycemia, target blood sugar values, concomitant medications, and lifestyle factors, for each advice on drugs, diet, and exercise. The DTMS software has facilities for notes on treatment goals and reminders for follow-up as well.

Frequent telemedicine follow-up. We provide three telemedicine follow-up options to the patients—via phone, e-mail, and secure website. These enable patients to report SMBG values and obtain treatment advice without a physical visit to the hospital. Patients are given 24/7 access to the DTMS team, with the primary contact being a diabetes educator, who coordinates follow-up with the patient within 24–48 h of his or her contacting the Center. Specialist advice, from the treating physician/dietician/nurse/pharmacist, is provided to the patient on an "as needed" basis for each telemedicine follow-up. Advice through DTMS includes modifications in insulin and OHA doses, diet and exercise, troubleshooting with usage of devices like insulin pens, glucometers, and diabetes care during concomitant illnesses otherwise under control, and other minor incidents like fever. In case of emergencies, patients are requested to use the nearest healthcare services. Each DTMS consultation also offers an opportunity for continuing education, counseling, and ensuring compliance with multiple drugs in diabetes.

Patient education. After the laboratory and physical evaluations, patients undergo education on various aspects of diabetes care at different stations, delivered by each member of the diabetes care team like diabetes educators, nurse educators, dietitians, pharmacists, and the psychologist. Patients initially spend an average of 30–60 min on glucometer training and 3 h on patient education programs on diet, exercise, and other aspects of diabetes care. Subsequent to the physical visit, patients are instructed to follow up via telephone, e-mail, or website. Each such teleconsultation provides an opportunity to the patient to clarify doubts regarding his or her treatment, lifestyle modifications, and use of medical devices such as a glucometer and insulin pen at every telemedicine follow-up and physical visit. Patients are also invited to half-day educational seminars of 4–5 h in duration once every 2 months.

The current study was undertaken to examine the effectiveness of DTMS, to examine the frequency of hypoglycemia with it, and to estimate extra costs incurred by the patient to take part in the program of intensive management. As mentioned, the dose titrations were not based on any algorithms. The aim was to obtain a sufficiently large enough sample to assess data from telemedicine follow-up in a heterogeneous sample representative of T2D patients eligible for an HbA1c target below 6.5%.

Subjects and Methods

We analyzed records of 1,000 T2D patients with at least 6 months of follow-up from the initial visit who had voluntarily enrolled in the DTMS program in our Center located in Trivandrum City, Kerala, in South India. Analyzed records were from patients 30–75 years old, who had HbA1c ≥ 6.5% at initial visit, reported SMBG values at regular intervals as per instructions, participated in diabetes education programs, and attended two additional scheduled visits in 6 months. Subjects with major co-morbid illnesses, brittle diabetes, or history of symptomatic hypoglycemic events were not eligible for intensive glycemic control and hence were excluded from the study. The study analyzed data from subjects coming to the Center for the first time.

The subjects were using the OneTouch® Ultra® glucose meter (LifeScan, a Johnson & Johnson Company, Milpitas, CA). SMBG values reported via telephone, e-mail, or website were entered into an electronic health record system prior to follow-up by the DTMS team. HbA1c values were measured using Bio-Rad (Hercules, CA) model D10 high-performance liquid chromatograph, and other biochemical measurements were made using a Cobas® C111 analyzer (Roche Diagnostics, Basel, Switzerland).

The extra costs involved in DTMS-based T2D management were estimated using costs of measuring and reporting SMBG values and the Center's charges for teleconsultation. It is possible that higher compliance to OHAs, insulin, and concomitant drugs occurs with DTMS, but we could not examine the costs of such higher drug compliance with current study design. Rather, we estimated the extra costs to patients for DTMS-based care when compared with that of traditional healthcare delivery. We converted currency values from Indian rupees (INR) to U.S. dollars (USD) using a rate of USD 1 = INR 47.30.

The direct saving from DTMS is the expense and time that would have been involved had the patient needed to physically visit the clinic for each consultation. The indirect saving would be any averted economic costs of future diabetes complications, by virtue of having better metabolic control. We could not estimate the indirect costs using the current study design.

The biochemical and physiological parameters measured on physical visits (HbA1c, lipid profile, fasting blood sugar, body mass index, serum creatinine, and blood pressure) were compared using the paired-sample t test. Proportions were analyzed using the χ^2 test. Hypoglycemia rates were estimated counting values <70 mg/dL in the electronic health records. The extra, recurring, direct costs involved with DTMS were calculated by assigning USD 0.57 per glucometer strip for SMBG, USD 0.02 per phone call/e-mail, and USD 3.25 per month for telemedicine services. Statistical analyses were done using Microsoft® (Redmond, WA) Excel and R.

Institutional ethics committee approval was obtained prior to the study.

Patient characteristics

Patients in the study were T2D patients coming to the Center for the first time. These included those with recently detected diabetes as well as those with long-standing diabetes who had been receiving treatment elsewhere. The average age of the patients was 53.2 years (SD = 9.8 years). Sixty-four percent of the patients were male. The duration of diagnosed T2D among enrolled patients ranged from 2 weeks to 37 years (mean = 10.9 years, SD = 7.1 years). Only 10 patients were single; the others were married. A majority of the patients ($n = 801$) had hypertension ($n = 242$), dyslipidemia ($n = 283$), and obesity ($n = 91$).

All subjects in the study were from the middle socioeconomic class who could afford regular drug treatment and had sufficient literacy to follow instructions. None of the subjects was from the very low income group. The subjects bought the glucometers themselves, and only the glucometer strips for the study were provided at a subsidized rate.

Follow-up

Over the course of 6 months, patients had two scheduled physical visits following their initial visits. There were also 66,745 SMBG values collected, reported through an average ± SD of 16.6 ± 2 telemedicine follow-ups per patient over 6 months, in between the physical visits. Patients got advice on diet and/or exercise on 70% of telemedicine follow-ups. Frequency of SMBG was individualized and more frequent in the initial months, with an average four times a day for 2.8 days a month. Each teleconsultation and physical visit ensured compliance to the use of all drugs including statins and antihypertensive agents if any. In DTMS, the targets of metabolic control for each patient is set at the start of therapy and then periodically modified based on duration of diabetes, presence or absence of co-morbid illnesses, basal HbA1c level, and history of hypoglycemia.

Treatment

Patients in the study were using OHAs with or without insulin. Regular monitoring and treatment modification as necessary are part of DTMS; as such, some patients had had the OHA and insulin components of their treatments changed over the course of 6 months. Specifically, 5% of patients were initiated with OHAs and given insulin also subsequently, 6% were initiated with insulin plus OHA(s) and subsequently taken off insulin, 68% of patients were on insulin plus OHA(s) throughout the 6 months, and 21% were given only OHA(s) during the 6 months.

Results

Patients showed a significant reduction in HbA1c from baseline at months 3 and 6 (Fig. 1). Mean HbA1c at the start of the study was 8.5 ± 1.4%. At the 6-month visit, the average HbA1c level was 6.3 ± 0.6%, giving a statistically significant reduction of 2.2% [$t(999) = 56.8$, $P < 0.0001$]. Twenty-seven percent of the enrolled patients had initial HbA1c > 9%, compared with 0.3% at the end of 6 months ($P < 0.0001$). There was no significant association of sex or age with HbA1c levels. HbA1c reduction was seen in all subgroups—irrespective of insulin use (Fig. 2).

The study also analyzed fasting blood sugar, serum creatinine, lipid profile, and blood pressure measured at three physical visits. All parameters showed statistically significant changes, of which the changes in low-density lipoprotein, total cholesterol, and fasting blood sugar appear most clinically significant (Table 1).

We examined a total of 66,745 SMBG values reported via phone or e-mail to DTMS. Of these, 261 values were

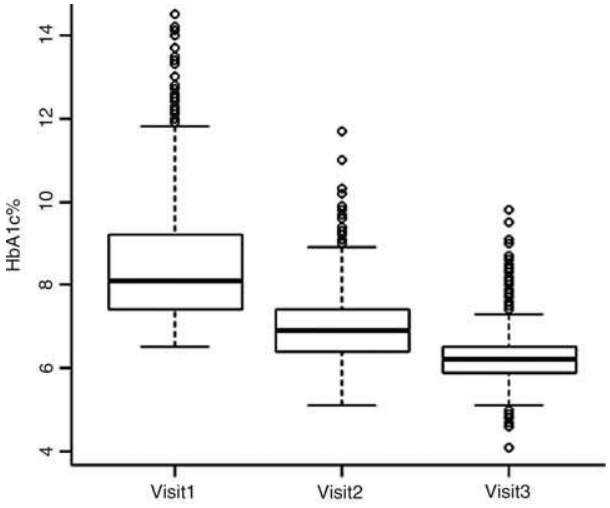

FIG. 1. Boxplot of glycosylated hemoglobin (HbA1c) values measured at three physical visits at Months 0, 3, and 6 ($n = 1{,}000$).

Table 1. Biochemical and Physiological Parameters Measured on Physical Visits

Variable	*Mean ± SD (n = 1,000) at*		*Change from Month 0 value*
	Month 0	*Month 6*	
FBS (mg/dL)	174 (59)	107 (19)	−67[a]
BMI (kg/m^2)	25.4 (3.8)	25.1 (3.5)	−0.3[a]
Blood pressure (mm Hg)			
Systolic	132 (19)	122 (12)	−9.6[a]
Diastolic	81 (10)	77 (7)	−4.5[a]
Serum creatinine (mg/dL)	0.9 (0.1)	0.8 (0.1)	−0.06[a]
LDL (mg/dL)	126 (40)	82 (20)	−44[a]
HDL (mg/dL)	42 (6)	46 (4)	+3[a]
Triglycerides (mg/dL)	137 (62)	102 (28)	−35[a]
Total cholesterol (mg/dL)	194 (42)	138 (17)	−56[a]

[a] $P < 0.01$.

BMI, body mass index; FBS, fasting blood sugar; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

<70 mg/dL. Eighty-four percent of patients reported no hypoglycemic events, 10% reported one hypoglycemic event each, 3.4% reported two events each, and 2.6% reported three to six values <70 mg/dL. The maximum number of values below 70 mg/dL for a patient was six ($n = 1$).The average number of hypoglycemia events recorded was 0.04/patient/month. None of the patients experienced severe hypoglycemic episodes requiring hospitalization.

The mean direct cost involved in SMBG was USD 38.03 ± 4.65 in 6 months (i.e., mean USD 6.34/patient/month [approximately INR 300]). The cost for reporting values was an average of USD 0.43 over 6 months or USD 0.07/patient/month (INR 3.31). Together with USD 3.25 per month for telemedicine services, recurring direct costs amounted to USD 9.66/patient/month (INR 456.92) for intensive management. In comparison, we estimate a physical visit to our Center for testing and consultation would cost at least USD 5–15 per visit.

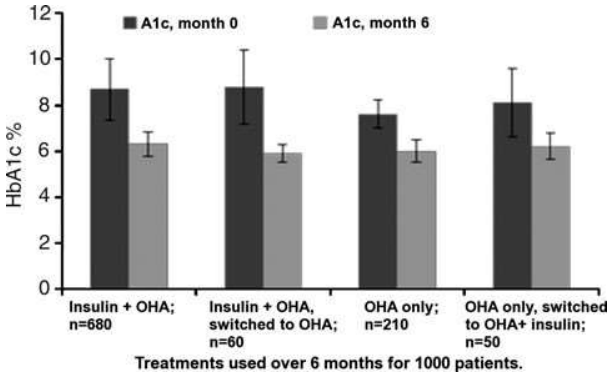

FIG. 2. Treatments used over a 6-month period for 1,000 patients. HbA1c, glycosylated hemoglobin; OHA, oral hypoglycemic agent.

Conclusions

The DTMS-based program is successful in achieving glycemic controls at par with internationally accepted treatment goals with minimal incidence of hypoglycemia. This success could be due to multiple components of the system. Each teleconsultation offers an opportunity for continuing diabetes education and drug compliance. The teleconsultations offer not only a chance for the doctor to fine-tune treatment, but also a chance for patients to develop more awareness and knowledge by interacting with diabetes educators, nurses, and dieticians. Frequent telemedicine follow-ups based on SMBG enable slow and steady titration of drug doses, reducing the risk of hypoglycemia. The rates of hypoglycemia reported are extremely low in DTMS. This overcomes a primary barrier in stricter glycemic control.

Although there are extra costs involved in SMBG and teleconsultation, the money and time saved in physical visits to the clinic that would have been needed in a traditional healthcare delivery model alone make up for the extra costs. Furthermore, it is proven that better glycemic control is very cost-effective in the long run to delay or prevent the complications of diabetes mellitus. We could evaluate cost of the monitoring and follow-up in this study, but not the cost of drugs, owing to wide variability of price among different branded generics of the same drug with time and across different points of purchase.

The main limitation of the study was that this was not a randomized, controlled trial for practical reasons. Most of the patients come to our Center to take advantage of the facility for telemedicine follow-up and intensive care. For this reason, we could not conduct a randomized controlled trial of this magnitude at our Center because patients attending the Center were not willing to forego a chance to get frequent follow-up. As a comparison, data from multiple public health camps organized by our Center indicate that T2D patients in the local populace are largely undertreated, with average HbA1c values being 9.4%.[7] Also to be considered is that many

of the patients enrolled in the study were patients with long-standing T2D (10.9±7.1 years) previously on treatment and still having an average HbA1c of 8.5% at the time of first presentation to our Center.

The current study examined clinical results in patients following the intensive management for 6 months; further studies are required to evaluate reasons for dropout and to evaluate ideal modes of follow-up for different types of patients. Smaller randomized controlled trials are also being planned to look at insulin dose and hypoglycemia under various frequencies of telemedicine follow up.

From our experience, the main limitation of DTMS is the effort required to successfully set up the infrastructure and operational facilities to be of 24/7 availability to patients. Although we have successfully implemented it to treat thousands of subjects, the scalability across multiple centers is a concern. Some patients also tend to rely on the service as a first resort for myriad problems, including emergencies, although we patiently advise otherwise. Some patients, especially the elderly, tend to make prolonged calls, which can be challenging for operations management. However, our experience is that after the initial period of intensive follow-up, the majority of patients develop disease awareness, knowledge, and skills to such a degree as to require less frequent follow-ups to maintain optimal metabolic control. Validation of the impact of such empowerment on disease outcomes requires long-term studies.

From the current study, there is statistically significant evidence that structured SMBG combined with DTMS is effective in achieving tight metabolic control with an insignificant incidence of hypoglycemia (0.04 episodes/patient/month). In T2D patients, DTMS appears effective, and the extra costs involved in this healthcare delivery model appear cost-effective in achieving customized targets of metabolic control.

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Author Disclosure Statement

The authors have no relevant conflict of interest to disclose. J.K. conceived the study, researched data, and reviewed and edited the manuscript. A.S. contributed to the discussion. P.B.S.P analyzed the data and wrote the manuscript. G.R. researched data and contributed to the discussion. S.J. contributed to the discussion.

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