ORIGINAL RESEARCH

A Pilot Study Using a Smartphone App to Allow Remote Monitoring of Glucose

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Introduction

Type 2 diabetes (T2DM) is a disease of unparalleled significance affecting over 387 million people worldwide.[1] Long-term complications of diabetes, such as retinopathy, nephropathy, neuropathy and cardiovascular disease can be mitigated with aggressive glucose control.[2] However, the modifications necessary to improve glucose control, such as lifestyle changes and day-to-day management with providers, can be challenging.

The use of mobile technology and telemedicine to enhance diabetes care has been an area of intense research and growth. Studies investigating mobile phone technology and its use in diabetes management have shown benefit in offering advice, education, support and clinical feedback via mobile phones to enhance glycemic control.[3,4] Smartphone applications (apps) for diabetes can not only help patients log glucose results, track food intake and provide self-care motivation, but they can help patients communicate glucose data with their healthcare providers in real time to make prompt, meaningful changes to diabetes medication regimens.

According to the Pew Research Center 52% of smartphone owners have used their phone to gather health information.[5] In 2015, the number of mobile app downloads was estimated to be over 75 billion.[6] The high prevalence of smartphone ownership and app downloads makes mobile technology an ideal modality for diabetes management tools.

We designed a pilot study to assess the feasibility of using a remote monitoring diabetes cell phone app for patients with poorly controlled type 2 diabetes. The goal of this study was to assess the feasibility of remote monitoring of glucose data for health care providers and patients.

Methods

We conducted a prospective pilot study from August 2017 to October 2017 at the UCLA Santa Monica Diabetes Center. English speaking patients aged 18-80 years of age with type 2 diabetes and hemoglobin A1c >9% within prior 3 months and on insulin therapy were eligible. Patients also had to own and be able to navigate a personal smartphone. Patients were excluded if they were pregnant, lactating, had a glomerular filtration rate <30 mg/dL, using artificial nutrition, had dementia or inability to sign informed consent or had a life expectancy of less than 12 months. The study was approved by the UCLA Institutional Review Board.

After signing informed consent, study participants conducted an initial intake and informational session with the study team (SG, undergraduate students). Study participants were given an iHealth glucose meter and test strips. The publicly available iHealth Gluco-Smart smartphone app was downloaded to their personal phone and patients were instructed on how to upload glucose data and navigate the app. Patients were asked to check their blood sugars up to four times per day. Glucose data was transmitted via bluetooth from the glucose meter to the app on the patient's phone. This data was monitored remotely by study personnel each week for six weeks using the iHealth website.

Study physicians contacted participants via telephone once weekly on a designated day to review glucose data and make medication adjustments. All glucose data and medication changes were documented in a telephone encounter that was forwarded to the patients' primary endocrinologist. Patients were scheduled to see their diabetes healthcare providers routinely based on medical necessity.

Results

Five patients with T2DM were recruited for the trial between August 2017 and October 2017. Table 1 summarizes the participants' baseline characteristics. Mean age was 51.4 years. During the six-week study, a total of 309 glucose values were collected and reviewed by study personnel. One patient (patient 4) did not upload glucose data (i.e., non-starter) and one patient (patient 5) ended the study early and returned the glucose meter on day 13 (i.e., non-completer). Table 3 displays glucose meter data and the number of telephone contacts made with each participant.

Given the small sample size, this study was not powered to assess changes in hemoglobin A1c. However, changes in hemoglobin A1c are reported for three of five patients with A1c available for review (ΔA1c range -0.8% to -5.8%, Table 3). Baseline HbA1c was obtained within 12 weeks of enrollment and follow-up hemoglobin A1c was obtained within 12 weeks post intervention.

All five patients were asked to complete a questionnaire at the end of the study via telephone. Results of the questionnaire are summarized in Table 2. In addition to the results displayed in Table 2 one participant did make suggestions to improve future smartphone apps. Most notably these included: 1) Additional

educational information 2) Warnings and recommendations regarding what to do with high or low glucose values 3) Reminders to check glucose.

Two of the five patients reported technical difficulties during the study. Patient 1 reported a malfunction with the meter on the first day of his study. However a visit with study personnel the following day revealed that he was not inserting the glucose test strip into the correct area. Patient 5 ended the study early and he retrospectively noted that he was experiencing difficulties with the remote monitoring system. He reported that his meter was not working properly. He was also frustrated with his diabetes in general and returned his glucose meter on day 13 of the study.

The resources required of study personnel was varied depending on the patient. Some patients had a more difficult time answering phone calls. These patients required increased utilization of study personnel and ultimately had fewer opportunities to adjust medication regimens. One factor was the inability of study personnel to schedule specific callback times due to non-study clinical duties. The overall time required of study personnel was estimated to be 5-6 minutes per patient per week (estimated range 2-10 minutes for all five patients including study non-starter).

Table 1: Baseline Characteristics

	Age	**Sex**	**Ethnicity**	**Oral/Non-Insulin Diabetes Medications**	**Long Acting Insulin Glargine**	**Short Acting Insulin**	**Pre-study A1c**
Patient 1	68	M	Caucasian	Metformin 500 mg bid with instruction to increase to 1 g bid	23 qhs with instruction to increase to attain goal fasting glucose	No	12.5%
Patient 2	58	F	Asian	Metformin 1 g bid Nateglinide 60 qac	Detemir 25 qhs	No	12.5%
Patient 3	32	M	Hispanic	Metformin 1 g bid	Glargine 18 qhs (increased day of study initiation from 15)	No	12.0%
Patient 4	38	M	Hispanic	Canagliflozin 100 mg qd	Detemir 25 qhs	Insulin aspart 15 qac	14.4%
Patient 5	61	M	Caucasian	Dulaglutide 1.5 mg weekly	Glargine 30 bid	Insulin aspart 15 qac and Novolog 5u with snacks	10.1%

Table 2: Questionnaire Results

Have you changed how you eat after participating in the study?	Positive Changes: 4 Negative Changes: 0 No Change: 0
Did you keep a food diary	Yes: 0 No: 4
How has your physical activity changed after participating in the study?	Increased: 1 Decreased: 0 No Change: 3
Did you log your activity?	Yes: 0 No: 4
Please rate user friendliness of smartphone application from 1 to 5 (1=not user friendly; 5=extremely user friendly)	Average score 4.75 of 5
Did you find the smartphone application easy to use? (1=difficult to use; 5=extremely easy to use)	Average score 5 of 5
How many DAYS per week would you like the application to record diet information?	Never: 1 1x/week: 0 2x/week 0 3x/week: 0 4x/week: 0 Daily: 3
Compared to standard office visits, do you think the application could help you gain control of your diabetes?	Yes: 4 No: 0 Maybe/Not Sure: 0
Did you find the smartphone application more convenient than reviewing blood sugar data with your medical provider in person?	Yes: 3* No: 0 Maybe: 0 No Answer: 1 *One participant who answered yes specified preference for combined approach

Table 3: Study Glucose and Contact Data

	Pre-Study A1c (%)	Post-Study A1c (%)	ΔA1c (%)	Cumulative Number of Glucose Readings	Average Glucose readings (mg/dL)	Outgoing Calls to Study Member	Phone Call to Review Glucose Data	Final Diabetes Regimen at Conclusion of Study
Patient 1	12.5	6.7	-5.8	101	129.2	6	6	Metformin 1 g bid
Patient 2	12.5	11.8	-0.8	62	234.9	10	2	Insulin detemir 28 qhs Metformin 1 g bid Anti-diabetic med 120 qac
Patient 3	12.0	8.4	-3.6	125	116.9	8	4	Metformin 1 g bid
Patient 4 (Study non-starter)	14.4	NA	NA	0	NA	6	0	Canagliflozin 100 qd Novolog 15 qac Levemir 25 qhs
Patient 5 (Ended Study Early)	10.1	NA	NA	21	245.3	6	1	Dulaglutide 1.5 mg weekly Insulin 30 bid Insulin aspart 15 qac Insulin aspart 5 with snacks

NA: Not Available
Qd: daily
Bid: twice daily
Qac: before meals
Qhs: before bedtime

Conclusion

This pilot assessed the feasibility of using a smartphone app to remotely monitor glucose data of patients. Patients found the iHealth smartphone app to be very user friendly with an average user friendliness rating of 4.75 of 5. Additionally, 100% of participants who used the remote monitoring system thought it could help them gain control of their diabetes. Notably, three patients that had post-study A1c levels available experienced a significant improvement in glycemic control during the study. This suggests that a smartphone app to remotely monitor glucose data may be used to enhance diabetes care.

From the patient perspective, the smartphone app was user friendly and increased convenience. From the provider and health system perspective, the smartphone app may pose initial technical challenges as well as additional time for reviewing blood glucose data and contacting patients. However, the time burden should decrease over time as staff are trained to use the program and clinical processes for following-up with patients are standardized. In fact, if the program was implemented on a larger scale it is possible that total time spent on patient care could decrease since patients would have brief weekly check-ins rather than frequent in-person visits. Nonetheless, if this program were implemented on a larger scale it is likely that some type of financial commitment would be required to allow practitioners sufficient time to review data and contact patients.

Possible interventions that would streamline communications between providers and patients include an automated insulin titration system based on glucometer data and a remote messaging system. This could significantly decrease the time

required of health care providers to monitor glucose levels and make necessary medication adjustments. Other features that may make the app more successful include additional educational resources, reminders to check fingersticks and diet logs. While none of the four patients who completed the survey logged their food intake during the study, three of the four patients noted that they would like diet information to be collected in the app on a daily basis.

This was a pilot study with a few limitations. First, the small sample size may not be representative of the general population. Second, patients self-selected into the study and some may have been more highly motivated to improve their diabetes care. For example, patients who used the app most frequently (>100 readings) had dramatic decreases in A1c (-3.6% and -5.8%).

In conclusion, this pilot study showed that it is feasible to monitor glucose data remotely and patients find remote monitoring convenient.

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