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Pilot Study Using Mobile Health to Coordinate the Diabetic Patient, Diabetologist, and Ophthalmologist

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Abstract

Background: In the United States, more than 25 million adults have diabetes, 40% of diabetics have diabetic retinopathy, and diabetes is the leading cause of blindness in people 20 to 74 years of age. Clinical trials have shown that strict control of blood glucose level and other risk factors delays diabetic retinopathy onset, progression, and vision loss.

Methods: Patients with Type 1 or Type 2 diabetes mellitus, access to an Apple iPhone or iPad, and no psychological or medical condition that would interfere with the study participated in a nonrandomized clinical trial using SightBook™, a free mobile app that enables self-measurement of visual function and creates a password-protected web account for each patient.

Results: Sixty patients enrolled in the clinical trial over a 6 month period. Twenty-six participants were men and 34 were women, with ages from 23 to 72 years (mean 45 ± 15) and diabetes duration of 1.5 to 50 years (mean 15.5 ± 11.5). Thirty-nine (65%) patients reported Type 1 diabetes and 21 (35%) patients reported Type 2 diabetes. Every patient established a personal web account on SightBook and invited participation of treating physicians; 51 (85%) patients completed the validated self-reported outcome assessments. Diabetologist examinations of 49 (82%) patients demonstrated systolic hypertension ($\geq$140 mgHg) in 20% and hemoglobin A1c $\geq$ 7.0% in 56%. Ophthalmology examinations of 45 patients showed visual acuity in the worse-seeing eye of < 20/40 in 18% and diabetic retinopathy in 42% of patients.

Conclusions: This clinical trial used a mobile health app to incorporate diabetic patient self-measurement of vision and coordinate the diabetic patient, diabetologist, and ophthalmologist for control of diabetes and diabetic retinopathy risk factors.

Keywords

app, coordinated care, diabetes, diabetic retinopathy, mHealth, mobile application

The World Health Organization estimates that at least 382 million people have diabetes mellitus.[1,2] In the United States, more than 25 million adults have diabetes, 40% of diabetics have some degree of diabetic retinopathy, and diabetes is the leading cause of new blindness in adults 20 to 74 years of age.[3-6] Clinical trials have demonstrated that strict control with near-normal blood glucose levels, blood pressure, and serum lipids delays diabetic retinopathy onset, retinopathy progression, and associated vision loss.[4,5,7-11]

Diabetic retinopathy usually progresses in a predictable manner from minimal structural manifestations to sight-threatening disease stages. When diabetic retinopathy severity warrants intervention, clinical trials have shown that timely and effective treatment decreases retinopathy-related vision loss and prevents 90% of blindness.[12] Recognizing the importance of risk factor control and the critical timing for diabetic retinopathy treatment, both the American Diabetes Association and the American Academy of Ophthalmology recommend screening eye examinations at regular intervals for all patients with diabetes (Table 1).[3,13]

In recent years, new possibilities for engaging patients in their own health care and coordinating health services have emerged from advances in mobile communication and

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Table 1. Recommended Eye Examination Schedule for Patients With Diabetes Mellitus.[3]

Diabetes type	Recommended time of first examination	Recommended follow-up[a]
Type 1	3-5 years after diagnosis	Yearly
Type 2	At time of diagnosis	Yearly

[a]Abnormal findings may dictate more frequent follow-up examinations.

increases in utilization of mobile technology. With more than 1 billion smartphones and 100 million tablets in use world-wide, mobile health (mHealth) has developed as a component of electronic health (eHealth).[1] The World Health Organization defines mHealth as "medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices."[14]

In a 2013 review, 8000 mHealth apps were listed at Apple iTunes for mobile devices.[15] More than 400 mHealth apps were related to diabetes mellitus with emphasis on self-management, diabetes education, and, in some instances, communication with the diabetes physician caregiver.[15,16] However, to our knowledge, no other mHealth app incorporates patient self-measurement of vision and coordination of the patient, diabetologist, and ophthalmologist to control diabetic retinopathy risk factors and timing of ophthalmology treatment.

We hypothesize that there is a role for using a mobile app that incorporates home vision testing and allows communication between multiple physicians in diabetic health care. The purpose of this study was to for testing the feasibility of using SightBook™, a free mobile app that test vision at home, in patients with diabetic retinopathy.

Methods

This prospective nonrandomized clinical trial took place at the University of California, Los Angeles (UCLA) in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and with approval of the UCLA Human Subject Protection Committee (HSPC 12-001117). The clinical trial is registered at clinicaltrials.gov (NCT 01983917).

The clinical trial utilized SightBook, a free mobile app developed by DigiSight Technologies, Inc (Portola Valley, CA, USA) that is compatible with iPhone, iPad, and other Apple devices, available at iTunes.com.[17,18] After installing the SightBook app, patients created a personal medical profile on a secure website. The process included registration and creating a unique password. Each patient invited his or her physicians to access the patient's secure site, upload data, and view the patient–physician profiles. Self-testing of vision using SightBook allowed measurement of multiple parameters: visual acuity, Amsler grid, contrast visual acuity, and color visual acuity (Figure 1).
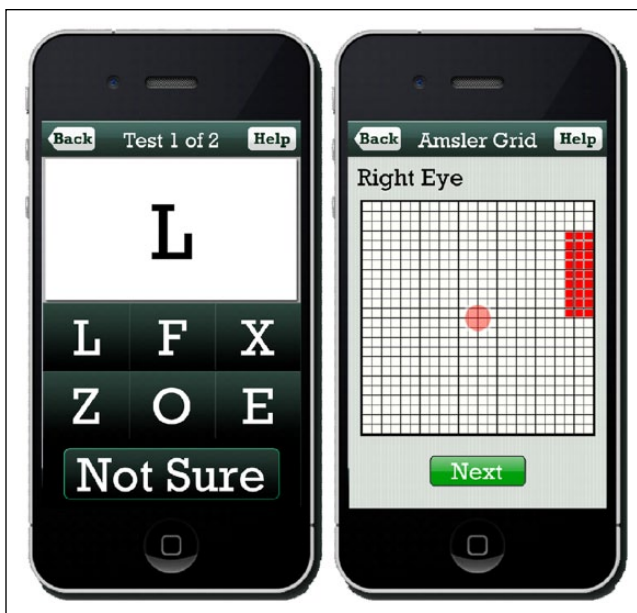

Figure 1. SightBook app images. (Left) Self-measurement of visual acuity by viewing "L" (above) at a specified distance and identifying the correct letter among the letter choices (below). (Right) Amsler grid assessment of central visual field by looking at the center circle and identifying distortion or absence of the regular pattern. Figure courtesy of DigiSight Technologies, Inc.

Patients were recruited over a 6-month time period by a certified study coordinator for the clinical trial from the Gonda (Goldschmied) Diabetes Center and the Jules Stein Eye Institute. Inclusion criteria were diagnosis of diabetes mellitus Type 1 or Type 2, age 14 to 75 years, access to an Apple mobile device (iPhone or iPad) with online capability, fluency in English language, ability to give informed consent, and willingness to participate. Patients under 18 years of age required a parental consent. Exclusion criteria were any social, psychological, or physical condition that would interfere with participation in or interpretation of the study.

Demographic data collected from each patient included age, gender, self-identified ethnicity, highest education level, annual income, marital status, and living situation. Once enrolled, participants were trained in use of SightBook by a certified study coordinator. Patients used SightBook for (1) self-measurement of visual acuity of each eye, (2) Amsler grid assessment for possible distortion in central vision, (3) recording of diabetes self-management, and (4) viewing of diabetes medical care and ophthalmology vision care information.

At baseline, patients completed validated questionnaires online to assess patient-reported outcomes hypothesized to improve with the intervention: (1) depressive symptoms (Patient Health Questionnaire; PHQ-9), (2) perceived competence in managing diabetes, and (3) illness perceptions regarding diabetes (Brief Illness Perception Questionnaire; Brief IPQ).[19-21]

For each patient, the diabetologist and ophthalmologist were invited to participate in the clinical trial by establishing

a SightBook account and providing clinical reports and test results from each patient encounter. The physician or study coordinator uploaded data onto the patient's individual SightBook account. The patient and participating physicians were able to view the coordinated online record of patient self-testing, physician notes, and pertinent laboratory test results.

Completion of the baseline record required that (1) the patient establish a secure SightBook web account, invite his or her diabetologist and ophthalmologist to participate in the clinical trial, and complete questionnaires; (2) the diabetologist report at least 1 patient office encounter; and (3) the ophthalmologist report at least 1 office encounter. Primary outcome of the clinical trial was the number of participating patients, diabetologists, and ophthalmologists who completed the baseline record. The study coordinator contacted the participating patients and physicians in person or by phone at least 3 times before the record was considered incomplete. Minimum follow-up for each patient was 3 months after enrollment.

Results

Sixty patients enrolled in the clinical trial consisted of 26 men and 34 women with an age range from 23 to 72 years (mean 45 ± 15 years). Regarding level of education, high school graduation, college degree, and postgraduate degree were reported in 100%, 75%, and 42% of patients, respectively.

Thirty-nine (65%) patients reported Type 1 diabetes and 21 (35%) patients reported Type 2 diabetes with disease duration of 1.5 to 50 years (mean 15.5 ± 11.5 years). At baseline, self-administered questionnaires (n = 51) indicated that patients on average reported mild depression (53% no depression, 29% mild depression, 8% moderate depression, 6% moderately severe depression, 4% severe depression, according to recommended cutoffs). Patients had moderate confidence in their management of diabetes. With regard to illness perceptions, patients on average reported moderate symptoms from diabetes and a moderate effect of diabetes on their lives and emotions; they had a somewhat higher perception of control over diabetes, understanding of and concern about the disease, and high confidence in their treatment (Table 2).

Baseline diabetology examination in 49 patients identified systolic hypertension (≥140 mm Hg) in 20% and diastolic hypertension (≥90 mm Hg) in 10% of patients (Table 3). Hemoglobin A1c was ≤7.0%, 7.1-10%, and >10.1% in 44%, 46%, and 10% respectively. Regarding blood lipid status, low density lipoprotein (LDL) was high (≥160 mg/dl) in 5%.

Baseline ophthalmology examination in 45 patients showed visual acuity in the worse-seeing eye of 20/40 or better, 20/50-20/200, and worse than 20/200 in 82%, 9%, and 9%, respectively (Table 4). Diabetic retinopathy was

Table 2. Patient-Reported Outcomes.[19-21]

	Average	SD	Range	Coefficient α
PHQ-9 Depression[a] (n = 49)	5.73	5.69	0-27	.89
Perceived Competence Scale[b] (n = 49)	21.02	5.45	8-28	.95

Illness perception[c]	n	Average	SD
How much has illness affected your life?	51	5.43	2.56
How much control do you feel you have over your illness?	51	6.06	2.01
How much do you think your treatment can help your illness?	51	8.47	1.42
How much do you experience symptoms from your illness?	51	5.39	2.55
How concerned are you about your illness?	51	7.78	2.36
How well do you understand your illness?	50	7.78	2.25
How much does your illness affect you emotionally? (eg, does it make your angry, scared, upset or depressed?)	50	5.20	3.12
Most important cause of illness (%)			
Genetics		50 (24/48)	
Environment		12 (6/48)	
Lifestyle (diet, exercise, stress)		19 (9/48)	
Other		19 (9/48)	

[a]Scale: 0 = *least depressed* to 27 = *most depressed*.
[b]Scale: 0 = *least competent* to 28 = *most competent*.
[c]Scale: 0 = *strongly disagree* to 10 = *strongly agree*.

Table 3. Diabetes Data Summary.[22-24]

		Range	% of participants
Systolic BP (mmHg)	140 and above	High	20.4 (10/49)
	120-139	Prehypertension	40.8 (20/49)
	Below 119	Normal	38.8 (19/49)
Diastolic BP (mmHg)	90 and above	High	10.2 (5/49)
	80-89	Prehypertension	34.7 (17/49)
	Below 79	Normal	55.1 (27/49)
Hb A1c (%)	10.1 and above	Diabetes	10.4 (5/48)
	7.1-10.0	Diabetes	45.8 (22/48)
	6.5-7.0	Diabetes	22.9 (11/48)
	Below 6.4	Prediabetes/normal	20.8 (10/48)
LDL (mg/dL)	160 and above	High	5.3 (2/38)
	130-159	Borderline high	7.9 (3/38)
	100-129	Near or above optimal	21.1 (8/38)
	Below 99	Optimal	65.8 (25/38)

Table 4. Ophthalmology Data Summary.[a]

Visual acuity[b]	No DR (%)	Mild NPDR (%)	Moderate NPDR (%)	Severe NPDR (%)	Inactive PDR (%)	Active PDR (%)	DME (total subjects)
Better than 20/40 (reading, driving), n = 37	62.2 (23/37)	18.9 (7/37)	5.4 (2/37)	2.7 (1/37)	5.4 (2/37)	5.4 (2/37)	4
20/50-20/200, n = 4	0.5 (2/4)	0.3 (1/4)	0.0	0.0	0.3 (1/4)	0.0	1
Worse than 20/200 (nonambulatory), n = 4	0.3 (1/4)	0.0	0.0	0.0	0.5 (2/4)	0.3 (1/4)	1

[a]The ophthalmologist data summary table includes data on 7 patients provided by optometrists.
[b]Visual acuity in the worse-seeing eye.

absent, mild, moderate, severe and proliferative in 58%, 18%, 4%, 2%, and 18% of patients, respectively. In addition, 4 patients with visual acuity of 20/40 or better had diabetic macular edema. Visual acuity did not consistently correlate with the degree of diabetic retinopathy or macular edema, showing that patients with 20/40 or better visual acuity may have diabetic retinopathy that warrants ophthalmologic treatment.

In regard to the primary outcome of the clinical trial, every patient downloaded SightBook, registered and created a unique password on SightBook, and invited the participation of treating physicians. In addition, 51 (85%) patients completed the validated questionnaires. Forty-nine (82%) of the participating diabetologists and 37 (62%) of the ophthalmologists completed the patient's baseline record by reporting at least 1 patient encounter.

Discussion

This pilot study used SightBook, a free mobile app, to incorporate self-vision testing and to increase communication between physicians caring for diabetic patients. Although there was great enthusiasm from patients to use the self-vision testing mobile app, there were several lessons learned that should be considered for future trials using mHealth for diabetic health care.

Visual acuity in diabetic retinopathy is primarily affected by diabetic macular edema (DME), and self-vision testing mobile apps should be targeted at patients with DME. Late stages of diabetic retinopathy can occur without symptoms or visual acuity changes and therefore visual acuity testing is not a sensitive or specific surrogate for detecting progression of diabetic retinopathy. In our study, only 13% of patients had DME so although patients were enthusiastic about testing their vision at home, progression of diabetic retinopathy was not well monitored by using the mobile app.

Physicians are already overburdened and short on time, and future use of mHealth should be streamlined to work with existing electronic medical record systems. In our study, upload of physicians' notes was done primarily by the research coordinator, which is not practical in real-life situations. Furthermore, physician participation that involves logging into the website to review individual

patients was not required for this study and would be difficult to obtain.

There are already mobile apps such as MyChart (Epic, Verona, WI, USA), which allow patients to access their own medical records via mHealth. However, to our knowledge, there is no mobile app that combines self-vision testing with their hospital based electronic medical record. The importance of changes in visual acuity at home as well as encouraging patient participation in health care may be an important innovation in diabetic health care.

Limitations of this study include the fact that the mobile app was not specifically designed for diabetic health care. Future trials should modify the mobile app to have laboratory values (ie, hemoglobin A1c, microproteinuria) recorded and interpreted for patient knowledge. In addition, incorporating Bluetooth glucose monitoring and other existing diabetic mobile apps would be useful.

Conclusion

In conclusion, this nonrandomized clinical trial is, to our knowledge, the first attempt at using a mobile app to incorporate self-measurement of vision into diabetes self-management. This pilot study elucidated a few of the challenges faced when incorporating mHealth as a component of long-term and multidisciplinary diabetes care. Additional enhancement of mHealth technology is needed to incorporate such mobile apps with the existing electronic medical record infrastructure and meet user expectations.

Abbreviations

App, application; BP, blood pressure; Brief IPQ, Brief Illness Perception Questionnaire; DME, diabetic macular edema; DR, diabetic retinopathy; eHealth, electronic health; Hb, hemoglobin; HIPAA, Health Insurance Portability and Accountability Act; mHealth, mobile health; NPDR, nonproliferative diabetic retinopathy; PDA, personal digital assistant; PDR, proliferative retinopathy; PHQ-9, Patient Health Questionnaire; UCLA, University of California, Los Angeles.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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